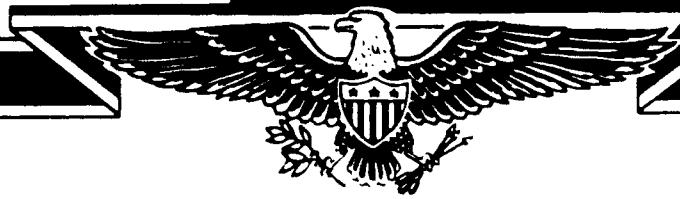


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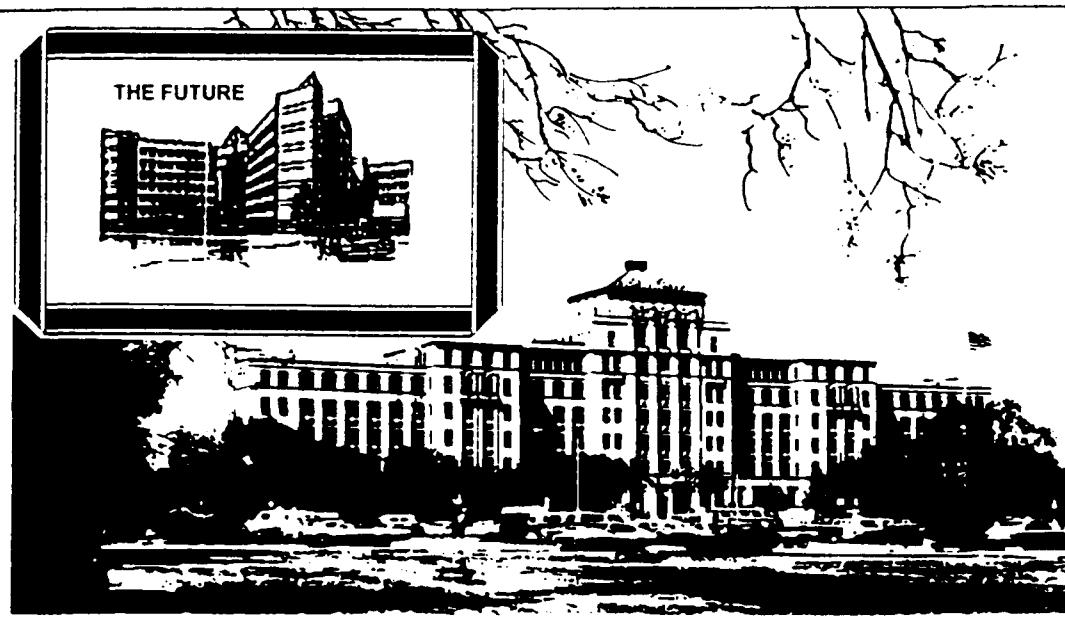
DEPARTMENT OF CLINICAL INVESTIGATION

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Gynecology Oncology Group

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Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: A-4-90      Status: Ongoing

Title: Botulinum Toxin Detection by Mouse Bioassay.

Start date: 7 Feb 90	Estimated completion date:
Principal Investigator: Michael Gray	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pathology and ALS	Associate Investigator(s): David Culak
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To establish and maintain a standing procedure for the mouse bioassay as a means for detecting Clostridium botulinum toxin in cultures, food products, serum and fecal specimens.

Technical Approach: Pairs of mice are selected and anesthetized with 2 ml of halothane in an enclosed glass container. The test suspension is injected IP into each of two mice using a 21 gauge, 1.25 inch needle. The mice recover from anesthesia within 1-2 minutes and are monitored on a daily basis up to 3 days.

Progress: #92101490 Swan Serum R/O Botulinum toxin.

Detail Summary Sheet

Date: 31 Dec 93

Protocol Number: A-5-90

Status: Ongoing

Title: Production of Mouse Positive and Negative Control Slides for Use in Rabies FRA test.

Start date: 7 Feb 90	Estimated completion date:
Principal Investigator: David Culak	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pathology and ALS	Associate Investigator(s): Michael R. Gray
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To produce negative and positive control slides for use in the Rabies Fluorescent Antibody Test (FRA).

Technical Approach: Twenty-five, 3-5 week old mice are anesthetized with halothane and are injected intracranially (IC) with .03 ml of CVS-11 rabies virus suspension utilizing a 1/4 inch, 27 gauge needle and tuberculin syringe. As mice exhibit symptoms of rabies and become moribund, they are euthanized by CO<sub>2</sub> asphyxiation. Brain and brain stem are collected, impression smears are prepared and held for future use.

Progress: Protocol in process of being rewritten to conform with new federal regulations and Army policies and to place protocols in the new CIRO animal use protocol format.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: A-7-90      Status: Completed

Title: Clinical Investigation on the Biodegradation of Lactide-Based Polymers in Rabbits.

Start date: 7 Mar 90	Estimated completion date:
Principal Investigator: Allan L. Bucknell, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Orthopaedics	Associate Investigator(s): Kevin Murphy, CPT, MC Danny Williams SSG Rene Cardona
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To evaluate the mechanical and biological behavior of biodegradable polymer rods synthesized at Smith and Nephew-Richards Medical Company after implantation in the dorsal muscle of rabbits.

Technical Approach: Thirty eight male rabbits will be used for the experiments. Four cylindrical rod samples will be implanted paraspinally in the dorsal musculature of each rabbit. Four thin circular discs will also be implanted by the side of the cylindrical implants for histological examination. The implantation site may be changed after mutual agreement but all animals will be treated identically.

Progress: All implants removed. Mechanical testing complete. Histologic slides prepared - to be reviewed.

**Detail Summary Sheet**

**Date:** 31 Dec 93      **Protocol Number:** A-9-90      **Status:** Ongoing

**Title:** Biosynthesis of Polyclonal Anti-peptide Antibodies in Rabbits.

<b>Start date:</b> 1 Jun 90	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Gerald Merrill	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Clinical Investigation	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_  
**Total number of subjects enrolled to date:** \_\_\_\_\_  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To develop antibodies to specific conformational regions of the model protein believed to be important in enzyme function and stability to aid in analysis of this procedure for studying protein structure.

**Technical Approach:** Four rabbits were immunized with synthesized peptides conjugated to poly-L-lysine to render them immunogenic. Three rabbits were immunized with a peptide corresponding to the amino terminal segment (residues 1-17) of rhodanese. The remaining rabbit was immunized with the tether sequence (residues 142-156) of rhodanese. In both cases, the peptide-poly-L-lysine conjugates were added to trehalose dimycolate and monophosphoryl lipid A (immune adjuvants) in oil-in-water micelles to aid in the immunization. Each rabbit was immunized every 2-4 weeks by IP and/or SC injections of immunogens. Prior to each immunization 2-10 ml of blood was obtained from each rabbit via cardiac puncture to screen for the presence of serum anti-peptide antibodies. The sera were screened by direct immunoassays in which either peptide or intact rhodanese was immobilized to microtiter plates as the capture antigen. Immunizations were continued for a period of 18 weeks.

**Progress:** Four rabbits are presently in use. These rabbits have been immunized with intact rhodanese (2 rabbits) or peptides (2 rabbits) as an oil-in-water adjuvant system in which antigen and the RIBI Adjuvant System proteins trehalose dimycolate and monophosphoryl Lipid mulsified into

A-9-90 (continued)

squalene-between 80 based liposomes. The immunogen was administered approximately once per month divided between IP, IM, and SC injections without anesthesia. Prior to each immunization approximately 10 ml of blood was obtained from each rabbit for screening and preliminary uses.

All four rabbits demonstrate a high titer antibody (detectable as a signal two times that of background by direct enzyme-linked immunoassay in which the purified antigen used in immunization is immobilized at serum dilutions greater than 1:100,000) which are specific for the immunizing antigen. Period bleedings are being frozen as a stock of specific high titer antibody for use in future studies requiring immunological detection of rhodanese and/or rhodanese fragments.

Previous immunizations are resulted in a low titer antibody directed against a 15 amino acid sequence of rhodanese. Two animals immunized with a 17 amino acid peptide sequence corresponding to the amino terminus of rhodanese failed to produce a detectable titer to the immunogen or intact rhodanese. Two additional animals died prior to initiation of immunizations.

Detail Summary Sheet

Date: 15 Dec 93      Protocol Number: A-10-90      Status: Completed

Title: An evaluation of Neurogenic Motor Evoked Potentials (NMEP) and Spinal Cord Protection in the Swine Model.

Start date: 1 Jun 90	Estimated completion date:
Principal Investigator: Paul D. Mongan, CPT, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/ Anesthesiology	Associate Investigator(s): Danny Williams SSG Rene Cardona
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$1,848.00

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To evaluate the use of neurogenic motor evoke potentials (NMEPs) as a noninvasive intraoperative monitor of spinal cord protection during thoracic aorta surgery.

Technical Approach: This study will be conducted on 45 swine divided into three equal groups. Group one will serve as a control. Group two will have cerebrospinal fluid drainage in an attempt to improve spinal cord blood flow (SCBF). Group three will have CSFD combined with intrathecal papaverine to improve spinal cord protection. After a left thoracotomy the descending thoracic aorta will be clamped distal to the left subclavian artery and NMEPs will be monitored. After loss of the NMEPs the distal aorta will be reperfused at varying intervals. NMEPs will be monitored for return and correlation with immediate postoperative neurologic function.

Progress: Phase I-III of this protocol were completed between June 1990 and January 1991. A subsequent addendum for additional funding was made to study a fourth group. After review of the progress of other investigations in this field, it was felt that this fourth group would not provide any significant information. Therefore, this group will not be studied.

**Detail Summary Sheet**

**Date:** 15 Dec 93      **Protocol Number:** A-15-90      **Status:** Completed

**Title:** Hemodynamic Effects of Dobutamine in a Porcine Hemorrhagic Shock Model.

<b>Start date:</b> 30 Aug 90	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> MAJ David W. Mozingo, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Surgery/SICU	<b>Associate Investigator(s):</b> James M. Lamiell, LTC, MC David W. Mozingo, CPT, MC Glen E. Gueller, SFC
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_  
**Total number of subjects enrolled to date:** \_\_\_\_\_  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) To determine the effect of dobutamine with small resuscitation fluid volume on resuscitation from hemorrhagic shock, a condition common on the battlefield.

2) To establish a dose response of the microcirculation to different dobutamine infusion rates as reflected by regional blood flow.

3) To establish that dobutamine plus small resuscitation fluid volume in hemorrhagic shock will resuscitate swine to physiologic endpoints.

**Technical Approach:** Piglets will be anesthetized, placed on an Airshields respirator and maintained on 100% oxygen. The pCO<sub>2</sub> will be kept in the normal range by periodic blood gas monitoring. Doppler flow probes will be placed on the aorta, renal artery, superior mesenteric artery, and hepatic artery to monitor regional blood flow. Four groups of six pigs will be studied. Medication for sedation will be ketamine 10 mg/kg IM. Additional anesthesia will be maintained with ketamine at 5 mg/kg.

**Progress:** Ten animals died in shock. Ten were unusable or uncollectable data secondary to technical problems with computer, blood gas analyzer, etc. 15 were used for study. Abstract present to Shock Society, Santa Fe, NM 13-16 Jun 1993.

**Detail Summary Sheet**

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**Date:** 15 Dec 93      **Protocol Number:** A-16-90      **Status:** Terminated

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**Title:** Maintenance of Mouse Bladder Tumor Cell Line and Assessment of Karyotype of MBT-2 Cells versus Time.

<b>Start date:</b> 12 Sept 90	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Timothy K. Dixon, MAJ, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Surgery/Urology	<b>Associate Investigator(s):</b> William Boykin, MAJ, MC Ian M. Thompson, MAJ, MC Eric S. Zeidman, MAJ, MC Paul Desmond, MAJ, MC
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_

**Total number of subjects enrolled to date:** \_\_\_\_\_

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To maintain MBT-2 cell line in tissue culture and in vivo in Osyngeneic C3H mice as a resource for current and future urologic investigations.

**Technical Approach:** The MBT-2 cell line will be maintained in tissue culture and in vivo using C3H mice. Also karyotype analysis will be obtained on the cells in culture every three months to assess chromosomal changes versus growth time in culture.

**Progress:** Technical methods for maintaining frozen MBT-2 cells in the laboratory and propagating the MBT-2 cells in tissue culture have been perfected eliminating the need for propagating/meintaining the tumor cell line by repeated inoculation of tumor cells into C3H mice. Frozen MBT-2 cells will be permanently banked/maintained by Mr. Chapa for use on future protocols on an as needed basis.

**Detail Summary Sheet**

**Date:** 15 Dec 93      **Protocol Number:** A-17-90      **Status:** Terminated

**Title:** Evaluation of Antitumor Activity of Cimetidine When Used in Conjunction with BCG Immunotherapy of Bladder Cancer in a Murine Model.

<b>Start date:</b> 12 Sep 90	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Steven C. Lynch, CPT, USAF, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Surgery/Urology	<b>Associate Investigator(s):</b> Ian M. Thompson, MAJ, MC Steven M. Dresner, MAJ, USAF, MC
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_

**Total number of subjects enrolled to date:** \_\_\_\_\_

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To investigate possible synergy between the immunotherapeutic effects of cimetidine and BCG.

**Technical Approach:** One hundred twenty female C3H/He mice will be provided tap water and chow ad libitum. The mice will be randomized into four groups.

Group 1 (controls) receive  $1 \times 10^4$  viable MBT-2 cells into the hind limb. This group will receive no further therapy.

Group 2 to receive continuous cimetidine (100 mg/kg/day) added to drinking water beginning three days before tumor inoculation.

Group 3 to receive BCG ( $1 \times 10^8$  CFU) intraperitoneally on a weekly basis for two weeks. This begins the day following tumor inoculation.

Group 4 to receive cimetidine three days before tumor inoculation, as in Group 2. Following tumor inoculation they receive BCG as in Group 3.

**Progress:** Very few animals developed tumors after the initial inoculation. This made further investigation with these animals invalid. The animals were disposed according to protocol.

**Detail Summary Sheet**

**Date:** 15 Dec 93      **Protocol Number:** A-5-91      **Status:** Terminated

**Title:** Alkalization of Lidocaine and its Effect on Plasma Levels in Guinea Pigs.

<b>Start date:</b> 9 Apr 91	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Samuel C. Sayson, CPT, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Surgery/Anesthesiology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_

**Total number of subjects enrolled to date:** \_\_\_\_\_

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To determine whether alkalization of lidocaine will affect plasma lidocaine levels obtained at predetermined times following intramuscular injection.

**Technical Approach:** The protocol has been modified to involve intraperitoneal injections of 2% lidocaine into rabbits. The volume of local anesthetic was too great to be injected into IM or intrapleural sites. Rabbits are used as the lidocaine assay require extracted blood volumes that were poorly tolerated by the guinea pig; therefore larger animals (rabbits) were chosen. The central artery of the rabbit ear was cannulated to extract samples used for plasma assay.

**Progress:** No new progress has occurred since the last review submitted in December 1991. Data at that point suggested no statistical difference in plasma lidocaine when intraperitoneal alkalinized vs nonalkalinized lidocaine is administered. Since 1992, several well done studies (animal & human) evaluating lidocaine plasma levels have shown that alkalinization of lidocaine does not increase plasma lidocaine to a significant degree. Given the overwhelming data published in the literature during the past year, it appears that continuing with this protocol would only sacrifice animals and investigation funds without likelihood of producing any publishable data. Lidocaine assay kits will be stored in hopes that future protocols might be written that would require measurement of serum lidocaine.

**Detail Summary Sheet**

**Date:** 15 Dec 93      **Protocol Number:** A-7-91      **Status:** Completed

**Title:** The Effect of Epidurally Administered Local Anesthetics on Differential Sensorimotor Neural Blockade Using Near-Field Cortical and Spinal Evoked Responses in Rabbits.

<b>Start date:</b> 29 Aug 91	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Joseph P. Ducey, MAJ, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Surgery/Anesthesiology	<b>Associate Investigator(s):</b> Paul Mongan, CPT, MC William Strong, MAJ, MC
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_  
**Total number of subjects enrolled to date:** \_\_\_\_\_  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To determine the selectivity (sympathetic, sensory and motor) of neural blockade produced by commonly used local anesthetics introduced into the epidural space.

2) To establish a dose-response relationship for sympathetic, sensory and motor blockade using epidurally administered local anesthetics in the rabbit.

**Technical Approach:** Five different local anesthetics in varying concentration will be studied: lidocaine, bupivacaine, etidocaine, 2-chloroprocaine, and mepivacaine. Combined somatosensory and motor evoked potential monitoring will be used to assess the onset, extent and conclusion of sensory and motor neural blockade. The different anesthetics will be compared in their ability to produce differential blockade by comparing the ratio of concentrations required to produce sensory and motor block.

**Progress:** The study is completed. We are preparing an abstract for presentation at the IARs meeting in the spring (1994). The following groups are complete with acceptable data:

Lidocaine 0.5%; Lidocaine 1.0%; Lidocaine 2.07%  
 Bupivacaine 0.125%; Bupivacaine 0.257%; Bupivacaine 0.57%  
 Chloroprocaine 1.07%; Chloroprocaine 2.07%.

A-91-07 (continued)

**SUMMARY OF RESULTS:**

(1) Lido effects sensory and motor EPs equally, as does Chloroprocaine. Bupiv products sparing of motor Eps in dilute concentrations.

(2) Motor and SSEPs can be followed serially when epidural Lido 0.5% or BVPiV 0.125% is administered. Abstract prepared for presentation at the IARS (International Anesthesiology Resident Society in April 1994.

**Detail Summary Sheet**

Date: 15 Dec 93      Protocol Number: A-92-01      Status: Completed

**Title:** Nasal Tip fixation: A Comparison of Suture Materials

Start date: 14 Nov 91	Estimated completion date:
Principal Investigator: MAJ Paul J. Davey, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Dept of Surgery/Otolaryngology	Associate Investigator(s): LTC Kweon I. Stambaugh, MC  LTC Clifford J. Hixon, VC

Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
 Total number of subjects enrolled to date: \_\_\_\_\_  
 Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

**Objective(s):** Object of study is threefold. The primary interest of this study is to evaluate various suture materials used to fixate alar cartilages and other nasal tip structures (one). To do this requires development of an animal model system for the suture evaluation (two), and an anatomic/histologic study of the healing process involved (three), with specific attention to the time frame of healing, strength of healing tissue, and relation of the various tissue involved in the healing process.

**Technical Approach:** A single incision will be made on the outer anterior ear surface and the cartilage exposed, incised, and sutured with the test suture material. 6-0 Nylon, vicryl, and chromic gut suture materials will be tested (i.e., 3 suture materials x 1 suture material per ear x 6 ears per suture material for a total of 18 ears) in 9 rabbits. This is followed by a healing period of 4, 8, and 12 weeks. The ears will be sampled by excising approximately 1/3 of the sutured cartilage at each of the 3 time points. The samples will then be processed for microscopic evaluation.

**Progress:** Animal model was developed, was successful. The various suture materials were tested. Microscopic Evaluation is still in progress. The study is now complete with respect to animal usage.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: A-92-02      Status: Ongoing

Title: Effect of Typically Applied Crystalline L-Lysine

Start date: 12 Mar 92	Estimated completion date: 2 Jan 93
Principal Investigator: Eleanor Ayala, MA	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Clinical Investigation	Associate Investigator(s): MAJ Earl Grant, Jr., MS
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine whether topical applications of crystalline L-lysine enhance the rate of wound contraction and rate of reepithelialization of punch biopsies using a hairless guinea pig model.

Technical Approach: Four male, 250-300g, euthymic hairless Hartley guinea pigs will be used. There is only one experimental group and all animals will be assigned to that group, given a number, and weight. All animals will be anesthetized and prepped for aseptic skin biopsies. There will be eight skin biopsy sites/guinea pig (four test sites and four contralateral control sites). All wounds will be blotted dry with sterile gauze.

Progress: Pilot study completed July 1993. Several observations were made during this pilot study. None of the L-lysine (free base, SIGMA) treated sites showed signs of infection. There was greater contraction and more granulation tissue in the control sites. Six animals were available at the beginning of this pilot study. One guinea pig died on day 1 when halothane anesthetic was used because accurate measurements of lesion diameters for wound contraction and central granulation evaluations could not be made of hand held animals. One guinea pig was sacrificed on day two when it was discovered that the animals had become infected. One guinea pig was a time to healing control.

A-92-02 (continued)

This pilot study has demonstrated that 1) L-lysine applications minimize wound contraction and may enhance wound healing; 2) that differences between treated and untreated sites may be more obvious if microscopic examination of wound sites are made 48 to 72 hours post wounding; 3) that careful attention should be made to the orientation and bisection of the tissue (perpendicular to the lines of contraction) when preparing samples for microscopic examination; and 4) that the wounds remain covered with the dressing until the samples are collected.

**Detail Summary Sheet**

**Date:** 31 Dec 93      **Protocol Number:** A-92-03      **Status:** Ongoing

**Title:** Effects of Desflurane on Neurogenic Motor Evoked Potentials in Swine

<b>Start date:</b> 15 Jun 92	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> MAJ Michael P. Hosking, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Surgery/Anesthesiology	<b>Associate Investigator(s):</b> MAJ Paul D. Mongan, MC
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_

**Total number of subjects enrolled to date:** \_\_\_\_\_

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** a) To determine the effects of desflurane on neurogenic motor evoked potential (NMEP) monitoring. b) To evaluate and characterize any dose related changes in the neurogenic motor evoked response associated with desflurane.

**Technical Approach:** One (1) experimental group consisting of 8 animals will be studied. Each animal will act as its own experimental control. After induction of anesthesia and placement of all monitoring electrodes a fifteen minute equilibration period will be observed to allow a return of physiologic variables to baseline. A baseline NMEP will then be recorded. Desflurane will then be administered in 0.25 MAC (MAC in swine is 9.4%) increments up to a maximum of 1.5 MAC, or until loss of the NMEP signal. A fifteen minute equilibration period will be allowed after the end tidal concentration of desflurane is stable at the desired level. A NMEP will then be recorded, and the concentration of desflurane increased to the next MAJ interval. An Axon Sentinel clinical evoked potential averager will be used to generate, amplify, and record NMEPs. NMEPs will be generated with a square wave pulses at a constant current of 25 mAmp delivered at a rate of 4.8/sec with a duration of 200 s. One hundred sweeps will be acquired through a band pass of 10-1500 Hz and averaged. Impedance will be maintained at less than 5000 ohms. The resulting signals will be observed on the oscilloscope and recorded on magnetic discs. All NMEPs will be recorded in triplicate and measured for amplitude and latency.

A-92-03 (continued)

Progress: Due to lack of equipment and time, no progress has been made on this protocol. We now have access to the equipment needed and as soon as the move to the new facility is accomplished time will be available to allow the investigators to proceed with this study.

**Detail Summary Sheet**

**Date:** 31 Dec 93      **Protocol Number:** A-92-06      **Status:** Completed

**Title:** The Effect of Slow Calcium Channel Blockade on Citrate Toxicity During Simulated Massive Transfusion in Swine

<b>Start date:</b> 18 Nov 92	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> CPT Jack Chavez, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Surgery/Anesthesiology	<b>Associate Investigator(s):</b> LTC Joseph P. Ducey, MC CPT Samuel Sayson, MC MAJ Paul D. Mongan, MC
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_

**Total number of subjects enrolled to date:** \_\_\_\_\_

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** a) To establish a porcine model for citrate cardiotoxicity. b) To establish a dose-response relationship between citrate dose (administered by continuous infusion) and cardiac performance. c) To determine the effect of preexisting calcium channel blockade on the dose-response relationship between citrate dose and cardiac performance.

**Technical Approach:** After induction of general anesthesia, all monitoring devices will be placed. Continuous intraoperative monitoring will include, ECG, arterial blood pressure (arterial line), central venous pressure, pulmonary artery pressure, rectal temperature, SpO<sub>2</sub> and end-tidal CO<sub>2</sub>. Upon initiation of the citrate infusions, the following data will be collected at 10 minute intervals for 60 minutes.

**Progress:** Study completed. Data analysis is in progress.

Detail Summary Sheet

Date: 15 Dec 93      Protocol Number: A-92-08      Status: Completed

Title: The Effects of Desmopressin on Myocardial Contractility in Swine

Start date: 16 Nov 92	Estimated completion date:
Principal Investigator: CPT Samuel Sayson, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s): CPT Jeffrey Baeuerle, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 13

Total number of subjects enrolled to date: 13

Periodic review date: 13      Review results:

Objective(s): To determine the effect of DDAVP on contractility.

Technical Approach: Ten animals will be used in this study. After induction of general anesthesia, all monitoring devices will be placed. Continuous intraoperative monitoring devices will be placed. Continuous intraoperative monitoring will include ECG, arterial blood pressure (arterial line), central venous pressure, pulmonary artery pressure, rectal temperature, SpO<sub>2</sub>, and end-tidal CO<sub>2</sub>. In addition, cardiac output, pulmonary artery wedge pressure, and pressure-diameter loops will be obtained at 0 (baseline, prior to any DDAVP therapy), 5, 15, 30, 45, 60, and 75 minutes after the initiation of DDAVP treatment.

Progress: Data for 9 animals were included for analysis. The other 4 animals did not provide usable data secondary to early death during surgical instrumentation and administration of DDAVP 16 mcg/kg revealed no change in EES (a measure of contractility) during the first hour following slow bolus. Furthermore, no changes in cardiac output, near arterial pressure or systemic vascular resistance (SVR) occurred. Administration of DDAVP has shown to have no hemodynamic effect in our endosystolic pressure volume relationship model. Given the fact that DDAVP typically causes a decrease in blood pressure in humans, we question whether or not our model is the appropriate model for studying the hemodynamic effects of DDAVP.

**Detail Summary Sheet**

**Date: 15 Dec 93      Protocol Number: A-93-01      STATUS: Completed**

**Title: Cardiopulmonary Effects of Nitric Oxide Synthase Inhibition and  
Inhaled Nitric Oxide in a Porcine Septic Shock Model.**

<b>Start date:</b>	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> MAJ David P. Ciceri, MC	<b>Facility:</b> Brooke Army Medical Center
<b>Department/Service:</b> Surgery/Critical Care Service	<b>Associate Investigator(s):</b> MAJ Frank M. Robertson, MC
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_

**Total number of subjects enrolled to date:** \_\_\_\_\_

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) To further investigate the adverse cardiopulmonary effects of nitric oxide (NO) synthase inhibition with N-nitro-L-arginine (NNLA); in particular, to study effects on right ventricular function. 2) To investigate the ability of inhaled nitric oxide to modulate the adverse cardiopulmonary consequences of systemic nitric oxide inhibition while maintaining the beneficial systemic effects.

**Technical Approach:** As outlined in the animal research protocol.

**Progress:** Protocol was terminated due to inactivity. Principal investigator was accepted into an anesthesiology residency effective 1 July 1993.

**Detail Summary Sheet**

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**Date: 15 Dec 93      Protocol Number: A-93-02      Status: Ongoing**

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**Title: Calcifying Oral Bacteria and Aortic Valve Calcification in a Rabbit Model.**

<b>Start date:</b>	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> COL David J. Cohen, MC	<b>Facility:</b> Brooke Army Medical Center
<b>Department/Service:</b> Surgery/Cardiothoracic Surgery Service	<b>Associate Investigator(s):</b> Mona Everett, Ph.D.
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_

**Total number of subjects enrolled to date:** \_\_\_\_\_

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) Verify that oral micro-organisms can cause calcification of the aortic valve. 2) Determine the nature of the pathology necessary to allow bacterial colonization, growth, and calcification in our experimental rabbit model. 3) Determine the time course of bacterial colonization, growth and calcification in our experimental rabbit model.

**Technical Approach:** As outlined in the research protocol.

**Progress:** There are no results to report at this time. Study is expected to be completed in February 1994.

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**Detail Summary Sheet**

**Date: 15 Dec 93      Protocol Number: A-93-03      Status: Ongoing**

**Title: Hypothyroid Induced Hypometabolic State as a Possible Diagnostic and Therapeutic Maneuver as Tested in a Mouse Model Utilizing PET Scanning**

<b>Start date:</b>	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> MAJ Kevin Carlin, MC	<b>Facility:</b> Brooke Army Medical Center
<b>Department/Service:</b> Medicine/Endocrinology	<b>Associate Investigator(s):</b> COL Albert Thomason, MC LTC Ian Thompson, MC Isidoro Chapa
<b>Key Words:</b> Mouse, Mus musculus, PET	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_

**Total number of subjects enrolled to date:** \_\_\_\_\_

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** Mice will be injected in the thigh with a mouse bladder cancer cell line and then randomized to an induced hypothyroid arm and a control arm. A PET scan will then be done to assess the metabolic status of the tumor burden verses the rest of the mouse body.

**Technical Approach:** Mouse bladder cancer cells maintained in cell cultures will be injected into the thigh of the mice. The mice will then be randomized to one of two groups: euthyroid and hypothyroid with the later induced by medication. PET scans using radioactive isotopes tagged glucose will then be done to see if the tumor masses are affected by thyroid hormone manipulation as compared to the rest of the mouse body.

**Progress:** A mouse was injected with tagged glucose and a PET scan done in very rough early stage manner, showing project is possible but still very difficult.

Detail Summary Sheet

Date: 15 Dec 93      Protocol Number: A-93-04      Status: Ongoing

Title: Production of Monoclonal Antibodies to Rhodanese and Chaperonin Epitopes in Ascites Tumors in BALB/c Mice for Use as Molecular Probes in Support of Clinical Investigation Protocol C-18-88

Start date: 30 Jul 93	Estimated completion date: Oct 94
Principal Investigator: Gerald Merrill, Ph.D.	Facility: Brooke Army Medical Center
Department/Service: Clinical Investigation	Associate Investigator(s): Kimberly Doody
Key Words: Mouse, <i>Mus musculus</i> , Monoclonal Antibodies, Ascites Tumors, Tumors, Rhodanese, Chaperonins	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: Review results:

Objective(s): To produce monoclonal antibodies to specific epitopes on rhodanese and the chaperonins (CPN<sub>60</sub> and CPN<sub>10</sub>) for use as biochemical molecular probes.

Technical Approach: As outlined in the research protocol.

Progress: CPN<sub>60</sub> and CPN<sub>10</sub> have been purified for use in immunization. No animals have yet been immunized. Ten mice will be ordered during Jan 94 for immunization.

Detail Summary Sheet

Date: 15 Dec 93      Protocol Number: A-93-05      Status: Ongoing

Title: Evaluation of a Prototype Double Lumen Multiorificed Catheter for Resuscitating Swine from a Lethal Air Embolism

Start date:	Estimated completion date:
Principal Investigator: MAJ Jon Hinman, MC	Facility: Brooke Army Medical Center
Department/Service: Surgery/Anesthesiology	Associate Investigator(s): MAJ Paul Mongan, MC
Key Words: Swine, Porcine, Sus scrofa, complications: air embolism, position: sitting, surgery: neurosurgery	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To evaluate the flow characteristics of the Cook Critical Care double lumen multiorificed catheter. 2) To establish the lethal dose of air (ml/kg) embolized into the sagittal sinus of a swine. 3) To evaluate the percentage of an air embolus aspirated by a Cook Critical Care double lumen multiorificed catheter. 4) To evaluate the ability of the Cook Critical Care double lumen multiorificed catheter to resuscitate a swine model from a lethal venous embolus. 5) To compare the results of a Cook Critical Care double lumen multiorificed catheter against an accepted standard; the Bunegin-Albin 16 Ga multiorificed catheter (flow, % aspiration, resuscitation).

Technical Approach: As outlined in the research protocol.

Progress: The results of this study are not available as of this time.

Detail Summary Sheet

Date: 15 Dec 93      Protocol Number: A-93-06      Status: Ongoing

Title: Titanium 13-13 Internal Fixation Plates in Comparison to CP Titanium Plates in the Healing of Long Bone Osteotomies in a Goat Model

Start date:	Estimated completion date:
Principal Investigator: CPT Christopher Vaughn, MC	Facility: Brooke Army Medical Center
Department/Service: Surgery/Orthopaedics	Associate Investigator(s): COL Allan Bucknell, MC CPT Matthew Horton, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine if Titanium 13-13 Plates perform more effectively in long bone fracture fixation than CP Titanium plates, decreasing the time to union, increasing ultimate strength and reducing stress shielding.

Technical Approach: A total of twenty (20) adult domestic goats will be studied. Plates will be placed on the lateral side of each femur. Plates used will be six to eight hole, narrow elongation plates. Six to eight goats will be sacrificed, and histologic and microbiologic testing will be performed.

Progress: We have plated 2 out of 20 goats. Progress is slow at this point. We still await funding. Awaiting more plates. The two goats that have been plated tolerated the procedure well.

Detail Summary Sheet

Date: 15 Dec 93      Protocol Number: T-9-86      Status: Ongoing

Title: Orthopaedic Microsurgery - A Training Protocol.

Start date: 29 Apr 86	Estimated completion date:
Principal Investigator: Allan L. Bucknell, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Orthopaedic	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: 66.30

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: 13 Mar 91      Review results: Continue

Objective(s): To train Orthopaedic Residents and maintain Orthopaedic Staff expertise at BAMC in the techniques used in microsurgery.

Technical Approach: The protocol is broken up into four phases. In the first phase, the trainee will learn basic suturing techniques using the operating microscope. The second phase will teach the techniques of microvascular anastomoses of arteries and veins, and vein grafts. The third phase will teach the technique of microneuroraphy, and the fourth phase will teach the technique of free tissue transfer using microvascular anastomoses.

Progress: Ongoing training for microsurgery. The protocol was revised as required by IACUC committee and was approved as written.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: T-10-86      Status: Ongoing

Title: Supervised Basic Abdominal and Vascular Surgical Experience.

Start date: 29 Apr 86	Estimated completion date:
Principal Investigator(vice Rosenthal) COL Robert Sollenberger, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/General Surgery	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: 910.00

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: 13 Mar 91      Review results: Continue

Objective(s): 1) To provide basic proficiency to junior housestaff in the handling of the GI and vascular systems before actually operating on humans.  
2) To increase the proficiency of more senior surgeons in the performance of seldom performed procedures, so as not to lose their skills.  
3) To learn new techniques and operations on animals before starting to use them on humans.

Technical Approach: Training is conducted as outlined in the protocol.

Progress: Continuing laboratory training in laparoscopic and open surgical procedures. Due to the age of the protocol revision was necessary to comply with regulatory requirements and protocol is currently under revision to conform with CIRO required format.

Detail Summary Sheet

Date: 15 Dec 93      Protocol Number: T-13-86      Status: Ongoing

Title: Swine Model for Technical Procedure Training of Emergency Medicine Residents.

Start date: 29 Apr 86	Estimated completion date:
Principal Investigator: Kevin G. Rodgers, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Emergency Medicine	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: 2,450.00

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: 13 Mar 89      Review results: Continue

Objective(s): To develop familiarity and competency in performing life saving technical skills applicable to the Emergency Room environment.

Technical Approach: Training is conducted as outlined in the study protocol.

Progress: Technical procedure training for Emergency Medicine residents continues to be a requirement by the Residency Review Committee (RRC) for accreditation. These labs are scheduled monthly and also benefit rotating students, interns and residents from other services. Protocol rewritten to adjust funding requirements. Received IACUC approval on 10 May 1993.

Detail Summary Sheet

Date: 15 Dec 93      Protocol Number: T-3-87      Status: Ongoing

Title: Abdominal Surgical Experience - Gynecology Service.

Start date: 19 Feb 87	Estimated completion date:
Principal Investigator: Allan R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics-Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$420.00

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: 13 Mar 91      Review results: Continue

Objective(s): To provide hands-on surgical experience for obstetrics and gynecology residents in emergency surgical techniques.

Technical Approach: Training conducted as outlined in the training protocol.

Progress: Monthly teaching sessions for medical students, interns and OB/GYN residents in surgical techniques, suturing, GI and GU procedures they are required to be familiarized with. To conform with regulatory requirements, the protocol was further revised.

**Detail Summary Sheet**

**Date:** 15 Dec 93      **Protocol Number:** T-4-87      **Status:** Ongoing

**Title:** Canine Utilization for Rigid Endoscopic Training.

<b>Start date:</b> 2 Mar 87	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Sylvester Ramirez, LTC, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Surgery/Otolaryngology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_  
**Total number of subjects enrolled to date:** \_\_\_\_\_  
**Periodic review date:** 13 Mar 91    **Review results:** Continue

**Objective(s):** 1) To provide hands-on experience to residents in Otolaryngology and Thoracic Surgery, (and possibly general surgery) in the art of rigid endoscopy.

2) To ultimately increase the quality of care to our endoscopy patients by decreasing their surgical risks through laboratory training.

3) To simulate the scenario of an esophageal or tracheobronchial foreign body, in a live, anesthetized animal, for the purpose of developing endoscopic foreign body removal skills.

**Technical Approach:** Training conducted as outlined in the protocol.

**Progress:** This is a training protocol for training residents in laryngoscopy, esophagoscopy, bronchoscopy and foreign body management. Over the last couple of years, we have not used any animals from BAMC since Wilford Hall had animals available. We still want to continue the protocol and protocol has been updated to conform with regulatory requirements.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: T-1-88      Status: Ongoing

Title: Oculoplastic Seminar and Laboratory and Wound Closure.

Start date: 7 Mar 88	Estimated completion date:
Principal Investigator: Donald A. Hollsten, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Ophthalmology	Associate Investigator(s):
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: 13 Mar 91      Review results: Continue

Objective(s): Provide advanced proficiency to members of the Brooke Army Medical Center House Staff in primary repair of oculoplastic wounds, learn new techniques and operations on animals before starting to use them on humans, and apply the principles of oculoplastic closure and management of ocular and oculoplastic trauma.

Technical Approach: Procedures performed include various types and depths of skin surface incisions and wounds, with subsequent closure utilizing flaps, grafts and Z-plasties.

Progress: Training of ophthalmology residents continues to be conducted on an annual basis. Protocol recently underwent major revisions in order to conform with regulatory requirements.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: T-92-01      Status: Ongoing

Title: Sensormedics Model 3100 High Frequency Oscillatory Ventilator Training using a Swine Model

Start date: 7 Oct 91	Estimated completion date:
Principal Investigator: Howard Heiman, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): This training protocol is designed to teach physicians and other health care professionals the basic knowledge required to use and operate a Sensormedics Model 3100 High Frequency Oscillatory Ventilator.

Technical Approach: As outlined in the training protocol.

Progress: Required annual review has not been received from principal investigator.

Detail Summary Sheet

Date: 15 Dec 93      Protocol Number: T-92-02      Status: Ongoing

Title: Pediatric Endotracheal Training Utilizing the Ferret Model

Start date: 20 May 92	Estimated completion date:
Principal Investigator: Stephen C. Inscore, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): This protocol is designed to teach physicians and other health care providers the basic knowledge and psychomotor skills required for efficient endotracheal intubation in children.

Technical Approach: Protocol designed to increase physician confidence in intubation skills and increase the efficiency with which invasive airway management is accomplished in emergencies.

Progress: 120-125 people were trained in pediatric airway management and intubation employing the ferret animal model. As a part of the PALS course, they have added a unique and extremely useful aspect in the respiratory failure station. Comments from students in the course evaluations over the last year have universally been positive and the ferrets have been the highlight of the course. The ferret model is especially beneficial to new incoming interns in both the Departments of Pediatric and Emergency medicine in learning pediatric airway skills.

Detail Summary Sheet

Date: 15 Dec 93      Protocol Number: T-92-03      Status: Terminated

Title: A Field Anesthesia Machine and the OHMEDA PAC Drawover Vaporizer

Start date: 1 Oct 92	Estimated completion date:
Principal Investigator: Douglas Anderson, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Surgery/Anesthesiology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): This training protocol is designed to provide anesthesiologists, nurse anesthetists and other health care professionals with clinical experience in the use of anesthesia equipment designed for field medical conditions.

Technical Approach: This protocol is designed to provide the operator with the experience and confidence required to provide anesthetic care to patients with this equipment.

Progress: Principal investigator requested approval for protocol termination. Approval was granted by IACUC committee.

Detail Summary Sheet

Date: 15 Dec 93      Protocol Number: T-92-04      Status: Transferred

Title: Emergency Medicine Trauma Skills Laboratory Using the Goat

Start date: 19 Nov 92	Estimated completion date:
Principal Investigator: Marco Coppola, CPT, MC	Facility: Darnall ACH, Ft Hood, TX
Department/Service: Emergency Medicine	Associate Investigator(s):
Key Words: ATLS GOAT	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost: \$500.00

Number of subjects enrolled during reporting period: 12

Total number of subjects enrolled to date: 12

Periodic review date: 1 Oct 93-94      Review results: N/A

Objective(s): Training protocol is designed to refresh Advanced Trauma Life Support (ATLS)-Emergency Medicine residents with basic skills in trauma resuscitation as required by the American Board of Emergency Medicine.

Technical Approach: This lab will provide the Emergency physicians and residents the training required in life-saving resuscitative procedures and will in turn provide optimal life saving care to critical patients.

Progress: Protocol transferred to Ft Hood.

Detail Summary Sheet

Date: 15 Dec 93      Protocol Number: T-93-01      Status: Ongoing

Title: Resident Training in Microsurgical Technique

Start date: 7 Dec 92	Estimated completion date:
Principal Investigator: MAJ Dan Gehlbach, MC	Facility: Brooke Army Medical Center
Department/Service: Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): This training protocol is designed to instruct resident physicians in the basic techniques of microsurgery required for reproductive surgery.

Technical Approach: During their three-month rotation on the Reproductive Endocrinology Service, OB-GYN resident physicians will perform or assist with approximately 10-12 operations in which the operating microscope is used for repair or anastomosis of the fallopian tube.

Progress: In Calendar year 93, seven residents and several interns and medical students received formal instruction in microsurgery through this protocol. Our protocol was tabled for several months while the Animal Lab was moving its new location, and also during the holidays.

**Detail Summary Sheet**

**Date:** 15 Dec 93

**Protocol Number:** T-93-02

**Status:** Ongoing

**Title:** Oral and Maxillofacial Surgery's Microneurosurgery Laboratory Utilizing Rats

<b>Start date:</b> Feb 93	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> COL James M. Startzell, DC	<b>Facility:</b> Brooke Army Medical Center
<b>Department/Service:</b> USA DENTAC	<b>Associate Investigator(s):</b> COL John P. McLaughlin, DC LTC Andrew A. Vorono, DC MAJ Matt Conklin, MC
<b>Key Words:</b> <i>Rattus norvegicus, micro-surgery, microneurosurgery, sciatic nerve, nerve repair, neurorrhaphy</i>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_

**Total number of subjects enrolled to date:** \_\_\_\_\_

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To introduce oral and maxillofacial surgery residents to microneurosurgery and to prepare them for the applications of those skills to human patients. To provide a method for the advancement and maintenance of microneurosurgery skills in previously training oral and maxillofacial surgery staff members.

**Technical Approach:** Prior to utilizing rats, one to two practical sessions will be conducted at the animal lab site. These sessions will introduce the residents to the operating microscope and loops, to microsurgery instruments and sutures, cloth and plastic materials, rather than animals. Animal phase of training will be scheduled based on the individual's progress in this pre-animal clinic.

**Progress:** Initial Animal Laboratory Phase was completed as scheduled in Jun 93. This consisted of six animal labs with bilateral sciatic nerve repairs on each animal. Anesthetic management and euthanasia were without incident. Doctors McLaughlin and Vorono PCS'd in Jun and Jul respectively. Lab was put on hold through the summer, as Dr. Startzell was the only staff present. Lab was subsequently delayed in the fall due to construction and transfer into the new facility and due to the IG inspection of the facility. Two animals have

T-93-02 (continued)

been done in the second phase of the animal lab; one at the old facility and one at the new facility. Animal labs were on hold through the Nov-dec holiday period and will restart in late Jan 94.

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Detail Summary Sheet

Date: 31 Dec 93

Protocol Number: T-93-03

Status: Transferred

Title: Certification Training: Advanced General Surgery Laparoscopic Procedures in the Porcine Model

Start date:	Estimated completion date:
Principal Investigator: MAJ Carol Ortenzo	Facility: Darnall Army Community Hospital
Department/Service:	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

This protocol was never initiated at BAMC. We were awaiting the required revisions from Dr. Ortenzo when the protocol was transferred to Fort Hood.

Detail Summary Sheet

Date: 31 Dec 93

Protocol Number: T-93-04

Status: Ongoing

Title: DEPMEDS War Surgery Training

Start date: 2 Oct 93	Estimated completion date: 2 Oct 93
Principal Investigator: COL Greg Bowman, MC	Facility: Brooke Army Medical Center
Department/Service: Department of Surgery	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To train personnel in: a) fundamental principles of abdominal and thoracic war surgery, and b) the use and limitations of the DEPMEDS environment and equipment.

Technical Approach: Animals will be transported by veterinary personnel to the DEPMEDS site in approved cages and vehicles. Induction and maintenance inhalant anesthesia and life support will be provided by anesthesia personnel with the assistance of veterinary personnel. Animals will be positioned in dorsal recumbency then steriley prepped and draped for aseptic surgery by operating room nursing personnel. Surgeons will perform splenectomy, small bowel resection with enterostomy, colon resection with end colostomy, thoracotomy, and pulmonary resection. Surgeons will perform open reduction/internal fixation of simulated diaphyseal fracture.

Progress: Departments of Nursing and Surgery personnel participated in a highly successful training exercise. Comments from participants generally fell along the line of "We need more training like this".

Date: 15 Dec 93 Proj No: SWOG 7804 Status: Ongoing

Title: Adjuvant Chemotherapy with 5-Fluorouracil, Adriamycin, and Mitomycin-C (FAM) vs Surgery Alone for Patients with Locally Advanced Gastric Adenocarcinoma.

Start Date FY 78	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Gastric adenocarcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 5	
Date of Periodic Review 18 Oct 93 Results Continue	

Objective(s): To determine the efficacy of adjuvant chemotherapy with 5-FU, Adriamycin and Mitomycin-C (FAM) on the disease-free interval and survival of patients with TNM stage-groups IB, IC, II and III gastric adenocarcinoma compared to potentially curative surgery alone.

Technical Approach: Therapy will follow the schema outlined in the protocol

Progress: This study is closed to new patient accrual, open for follow up purposes only.

**Detail Summary Sheet**

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Date: 15 Dec 93 Proj No: SWOG 7808 Status: Ongoing

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Title: Combined Modality Treatment for Stages III and IV. Hodgkin's Disease  
MOPP # 6.

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Start Date FY 79	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Hodgkin's Disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 13	
Date of Periodic Review 18 Oct 93 Results Continue	

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Objective(s): 1) To attempt to increase the complete remission rate induced with MOP-BAP alone utilizing involved field radiotherapy in patients with Stages III and IV Hodgkin's disease achieving a PR at the end of 6 cycles of MOP-BAP. 2) To determine if immunotherapy maintenance with levamisole or consolidation with low dose involved field radiotherapy will produce significantly longer remission durations over a no further treatment group when CR has been induced with 6 cycles of MOP-BAP in Stages III and IV Hodgkin's disease.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual. However, it will remain open for follow up purposes only.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 7827 Status: Ongoing

Title: Combined Modality Therapy for Breast Carcinoma, Phase III.

Start Date FY 80	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Breast Carcinoma	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 61	
Date of Periodic Review 18 Oct 93 Results Continue	

Objective(s): 1) To compare the disease-free interval and recurrence rates in estrogen receptor positive (ER+) premenopausal patients with Stage II disease, using combination chemotherapy alone versus chemotherapy and oophorectomy. 2) To compare the disease-free interval and recurrence rates in estrogen receptor positive postmenopausal patients with Stage II disease, using combination chemotherapy plus tamoxifen versus tamoxifen alone versus combination chemotherapy alone. 3) To compare the disease-free interval and recurrent rates in all estrogen receptor negative (ER-) patients with Stage II disease using one versus two years of combination chemotherapy.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This study is closed to new patient accrual. However, it will remain open for follow up purposes.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8216/38 Status: Ongoing

Title: Comparison of BCG Immunotherapy and Adriamycin for Superficial Bladder Cancer, Phase III.

Start Date FY 85	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian M. Thompson, MAJ, MC
Key Words: Cancer, Bladder	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): 1) To compare the effectiveness of intravesical BCG immunotherapy with intravesical adriamycin chemotherapy with respect to disease-free interval and two-year recurrence rate. 2) To compare the toxicity of topical immunotherapy and chemotherapy. 3) To obtain experience regarding disease-free interval and the recurrence rate in patients who develop tumor recurrence and are then crossed over to the alternative treatment arm.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for follow up purposes only.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8229/30 Status: Ongoing

Title: Combined Modality Therapy for Multiple Myeloma, VMCP-VBAP for Remission Induction Therapy: VMCP + Levamisole vs Sequential Half-Body Radiotherapy + Vincristine-Prednisone for Maintenance or Solidation. Evaluation ..... Phase II

Start Date FY 83	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Myeloma, multiple	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 18	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): 1) To compare the effectiveness of two intermittent pulse schedules of the chemotherapy combination of Vincristine, Melphalan, Cyclophosphamide and Prednisone (VMCP) plus Vincristine, BCNU, Adriamycin and Prednisone (VBAP) (alternating versus syncopated) for the induction of remissions in previously untreated patients with multiple myeloma. 2) For patients proven to achieve remission (at least 75% tumor regression after induction), to compare the value of 12 months of chemoimmunotherapy maintenance, VMCP + Levamisole, versus a consolidation program consisting of sequential half-body radiotherapy along with Vincristine and Prednisone followed by unmaintained remission. 3) For patients who only achieve improvement (50%-74% tumor regression) on chemotherapy induction, to determine whether sequential half-body radiotherapy with Vincristine.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for follow up purposes only.

**Detail Summary Sheet**

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**Date: 15 Dec 93    Proj No: SWOG 8294    Status: Ongoing**

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**Title: Evaluation of Adjuvant Therapy and Biological Parameters in Node Negative Operable Female Breast Cancer.**

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<b>Start Date</b> <b>FY 83</b>	<b>Est Comp Date:</b>
<b>Principal Investigator:</b> Timothy J. O'Rourke, LTC, MC	<b>Facility:</b> Brooke Army Medical Center
<b>Dept/Svc:</b> Department of Medicine/Oncology	<b>Associate Investigators:</b>
<b>Key Words:</b> Cancer, Breast Node Negative	
<b>Accumulative MEDCASE</b>	<b>Est Accumulative</b>
<b>Cost:</b>	<b>OMA Cost:</b>
<b>Number of Subjects Enrolled During Reporting Period:</b> 0	
<b>Total Number of Subjects Enrolled to Date:</b> 33	
<b>Date of Periodic Review</b>	<u>18 Oct 93</u> <b>Results</b> <b>Continue</b>

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**Objective(s):** 1) To assess the impact of short-term intensive chemotherapy with CMFP to prevent disease recurrence and prolong survival in N- patients with any size ER- tumor and N- patients with ER+ tumors whose pathological size is greater than or equal to 3 cm. 2) To assess the impact of surgical procedures, ER status, menopausal status and tumor size. 3) To develop guidelines referable to histopathological features of N- tumors which are reproducible and assess their prognostic impact for disease-free survival and survival.

**Technical Approach:** Therapy will follow the schema outlined in the protocol.

**Progress:** This study is closed to new patient accrual, open for follow up purposes only.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8300 Status: Completed

Title: Treatment of Limited Non-Small Cell Lung Cancer: Radiation vs Radiation plus Chemotherapy (FOMi/CAP), Phase III.

Start Date FY 85	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Non-small cell lung cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 10	
Date of Periodic Review 19 Oct 92	Results Continue

Objective(s): 1) To compare combination chemotherapy plus radiotherapy to radiotherapy alone for patients with limited, non-small cell lung cancer (NSCLC) in a randomized study with stratification for known important prognostic factors with regard to response rate, response duration and survival duration. 2) To determine the toxicity of radiotherapy plus FOMi/CAP relative to radiotherapy alone for patients with limited NSCLC. 3) To evaluate the responsiveness of small tumor burdens to FOMi/CAP (i.e., less than metastatic disease).

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is open for follow up purposes only.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8309 Status: Ongoing

Title: Autologous Marrow Transplantation for the Treatment of Non-Hodgkin's Lymphoma, Phase II.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Lymphoma, Non-Hodgkin's	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 18 Oct 93 Results Continue	

Objective(s): To determine the therapeutic potential of high-dose cyclophosphamide and total body irradiation followed by autologous marrow transplantation (AMT) in patients with an otherwise poor prognosis for cure in the specific lymphoma disease categories.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8313 Status: Ongoing

Title: Multiple Drug Adjuvant Chemotherapy for Patients with ER Negative Stage II Carcinoma of Breast, Phase III.

Start Date FY 84	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Breast Cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 9	
Date of Periodic Review 18 Oct 93 Results Continue	

Objective(s): 1) To compare through a randomized prospective study, the recurrence rates and disease-free intervals (DFI) for postoperative axillary node positive estrogen receptor negative (ER-) breast cancer patients given adjuvant therapy with either short term intense chemotherapy (FAC-M) or one year standard chemotherapy (CMFVP). 2) To compare the effect of these two adjuvant therapies on survival. 3) To compare the relative toxicity of the two therapies.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8326/27 Status: Ongoing

Title: Evaluation of Combination Chemotherapy Using High Dose Ara-C in Adult Acute Leukemia and Chronic Granulocytic Leukemia in Blastic Crisis, Phase III.

Start Date FY 85	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Leukemia, adult acute Leukemia, chronic granulocytic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 18 Oct 93 Results Continue	

Objective(s): 1) To compare the effectiveness of three different drug combinations using high dose Ara-C alone or high dose Ara-C in combination with m-AMSA or Mitoxantrone for remission induction in relapsed adult leukemias including both acute non-lymphocytic leukemia, chronic granulocytic during accelerated or blastic phase, as well as untreated secondary acute leukemias. 2) To monitor the side effects of the above combination chemotherapy schedules.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study remains open for followup purposes.

**Detail Summary Sheet**

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**Date:** 15 Dec 93    **Proj No:** SWOG 8393    **Status:** Ongoing

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**Title:** MEL 82 323, National Intergroup Protocol for Intermediate Thickness Melanoma.

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<b>Start Date</b> FY 84	<b>Est Comp Date:</b>
<b>Principal Investigator:</b> Timothy J. O'Rourke, LTC, MC	<b>Facility:</b> Brooke Army Medical Center
<b>Dept/Svc:</b> Department of Medicine/Oncology	<b>Associate Investigators:</b>
<b>Key Words:</b> Melanoma	
<b>Accumulative MEDCASE</b>	<b>Est Accumulative</b>
<b>Cost:</b>	<b>OMA Cost:</b>
<b>Number of Subjects Enrolled During Reporting Period:</b> 0	
<b>Total Number of Subjects Enrolled to Date:</b> 5	
<b>Date of Periodic Review</b> <u>18 Oct 93</u> <b>Results</b> <u>Continue</u>	

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**Objective(s):** 1) To determine the safest excision margins around the primary melanoma. 2) To evaluate the management of the regional lymph nodes (immediate vs delayed lymphadenectomy). 3) To evaluate the relative prognostic value of various histopathological parameters of melanoma.

**Technical Approach:** Therapy will follow the schema outlined in the protocol.

**Progress:** This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8406 Status: Ongoing

Title: Evaluation of Esorubicin (4' Deoxydoxorubicin) in Malignant Lymphoma, Phase II.

Start Date FY 85	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Lymphoma, malignant	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): 1) To determine the response rate and response duration of malignant lymphoma treated with Esorubicin. 2) To define the qualitative and quantitative toxicities of Esorubicin administered in a Phase II study.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8507 Status: Ongoing

Title: Maintenance versus no Maintenance BCG Immunotherapy of Superficial Bladder Cancer, Phase III.

Start Date FY 86	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian M. Thompson, MAJ, MC
Key Words: Bladder cancer	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	12
Date of Periodic Review	18 Oct 93
Results	Continue

Objective(s): 1) To compare the effectiveness of intravesical and percutaneous BCG immunotherapy given on a maintenance versus a no maintenance schedule with respect to disease free interval and rate of tumor recurrence in patients with transitional cell carcinoma of the bladder. 2) To assess the toxicity of maintenance and no maintenance BCG immunotherapy.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8509 Status: Ongoing

Title: Evaluation of Menogaril in Adenocarcinoma of the Prostate, Phase II.

Start Date FY 86	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian M. Thompson, MAJ, MC
Key Words: Adenocarcinoma, Prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 8	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): 1) To assess the antitumor activity of Menogaril in patients with advanced adenocarcinoma of the prostate. 2) To define the qualitative toxicities of menogaril administered in a Phase II study.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

**Detail Summary Sheet**

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Date: 15 Dec 93 Proj No: SWOG 8515 Status: Ongoing

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Title: Evaluation of Menogaril in Non-Hodgkins Lymphoma, Phase II.

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Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Non-Hodgkins, Lymphoma	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 18 Oct 93 Results Continue	

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Objective(s): 1) To determine the response rate and response duration for favorable and unfavorable histology Non-Hodgkin's lymphoma (NHL) treated with Menogaril. 2) To define the qualitative and quantitative toxicities of Menogaril administered in a phase II study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of non-Hodgkin's lymphoma with at least one site of bidimensionally measurable disease. Patients must have failed and recovered from potentially curable treatment. Patients with a cumulative dose of Adriamycin  $> 250 \text{ mg/m}^2$  are not eligible for this study. Allowable prior chemotherapy depends on disease type. Patients will be stratified according to histology: unfavorable histology NHL vs favorable histology NHL. Therapy will follow the schema outlined in the study protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8516 Status: Ongoing

Title: A Phase III Comparison of CHOP vs m-BACOD vs ProMACE-CytaBom vs MACOP-B in Patients with Intermediate or High-Grade Non-Hodgkin's Lymphoma.

Start Date FY 86	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Non-Hodgkin's lymphoma, high-grade	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	13
Date of Periodic Review	18 Oct 93 Results Continue

Objective(s): 1) To compare in a randomized Group-wide setting the complete response rate, response duration and survival of patients with intermediate and high-grade non-Hodgkin's lymphoma treated with one of four combination chemotherapy regimens: CHOP, m-BACOD, ProMACE-CytaBOM, or MACOP-B. 2) To compare the toxicities of each regimen in this patient population.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8520 Status: Ongoing

Title: Cis-Diamminedichloroplatinum II: Methotrexate and Bleomycin in the Treatment of Advanced Epidermoid Carcinoma of the Penis, Phase II.

Start Date FY 87	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian M. Thompson, MAJ, MC
Key Words: Carcinoma, epidermoid	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): 1) To determine the response rate in patients with advanced epidermoid carcinoma of the penis treated with cis-platinum, methotrexate, and bleomycin. 2) To evaluate the toxicity of this three-drug combination.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study will be closed in the near future. There have been some responses seen.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8573 Status: Ongoing

Title: Treatment of Limited Small Cell Cancer with Concurrent Chemotherapy Radiotherapy and Intensification with High Dose Cyclophosphamide.

Start Date FY 86	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, small cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 6	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): 1) To estimate the response rate and survival of patients with limited small cell lung cancer when treated with concurrent chemo-radiotherapy followed by chemotherapy and late intensification with high dose cyclophosphamide. 2) To assess the toxicity of this treatment program.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8590 Status: Ongoing

Title: Phase III Study to Determine the Effect of Combining Chemotherapy With Surgery and Radiotherapy for Resectable Squamous Cell Carcinoma of the Head and Neck.

Start Date FY 85	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Squamous cell carcinoma of head and neck	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	6
Date of Periodic Review	18 Oct 93 Results Continue

Objective(s): 1) To test whether the addition of chemotherapy to surgery and radiotherapy prolongs disease-free survival and survival between the two study groups. 2) To test whether the addition of chemotherapy to surgery and radiotherapy increases local control rates at the primary site and/or the cervical neck nodes. 3) To determine if the patterns of failure have been changed with the addition of chemotherapy.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8591 Status: Ongoing

Title: NCI Intergroup #0035, An Evaluation of Levamisole Alone or Levamisole plus 5-Fluorouracil as Surgical Adjuvant Treatment for Resectable Adenocarcinoma of the Colon.

Start Date FY 85	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Adenocarcinoma of colon	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 15	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): To assess the effectiveness of levamisole alone and levamisole plus 5-fluorouracil as surgical adjuvant regimens for resectable colon cancer by comparison with untreated controls.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study remains open for followup.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8598 Status: Ongoing

Title: Prospective Trial for Localized Cancer of the Esophagus: Comparing Radiation as a Single Modality to the Combination of Radiation Therapy and Chemotherapy, Phase III Intergroup.

Start Date FY 87	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, esophagus	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): 1) To determine the role of chemotherapy for a potentially curable subset of patients with squamous cell cancer of the esophagus. 2) To determine if the patterns of recurrence for patients treated with the combination of chemotherapy and radiation differs from those patients treated with radiation alone.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study remains open for followup.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8600 Status: Ongoing

Title: A Randomized Investigation of High Dose versus Standard Dose Cytosine Arabinoside With Daunorubicin in Patients With Acute Non-Lymphocytic Leukemia, Phase III.

Start Date FY 87	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Leukemia, acute, non-lymphocytic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 5	
Date of Periodic Review 18 Oct 93 Results Continue	

Objective(s): 1) To compare among patients with acute non-lymphocytic leukemia, the rate of complete remission produced by induction regimens of either standard dose Cytosine Arabinoside and Daunorubicin or high-dose Cytosine Arabinoside and Daunorubicin. 2) To compare the durations of complete remission and of disease-free survival among patients who each receive one of three combinations of induction and consolidation regimens. 3) To determine the comparative toxicities of these three programs of induction and consolidation.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8621 Status: Ongoing

Title: Chemo-Hormonal Therapy of Postmenopausal Receptor-Positive Breast Cancer, Phase III.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Breast	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): 1) To compare initial combined chemo-hormonal therapy with initial hormonal therapy with respect to survival. 2) To compare initial chemo-hormonal therapy using tamoxifen with that using DES with respect to survival. 3) A secondary goal is to compare combined chemo-hormonal therapy with initial hormonal therapy with respect to response in patients with measurable disease.

Technical Approach: Patients must have clinical or histologic confirmation of recurrent or disseminated breast cancer, with tumor positive for estrogen receptor or progesterone receptor. Patients with completely dissected disease or with a life threatening visceral disease will be ineligible. Therapy will follow the schema outlined in the study protocol.

Progress: This study is closed, open for followup purposes only.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8692 Status: Ongoing

Title: Therapy in Premenopausal Women with advanced, ER Positive or PgR Positive Breast Cancer: Surgical Oophorectomy vs. the LH-RH Analog, Zoladex: Phase III, Intergroup.

Start Date FY 89	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Breast	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): 1) To compare the time to treatment failure and survival of medical castration using Zoladex with surgical castration in premenopausal women with advanced, ER + or PgR + breast cancer. 2) To compare the response rate of the two treatments. 3) To assess the response rate to surgical castration in patients failing to respond to or relapsing on Zoladex, and the response rate to Zoladex in patients failing to respond to or relapsing on surgical castration. 4) To compare toxicities of medical castration and surgical castration. 5) To assess the value of post-treatment hormone levels (LH, FSH and estradiol) in predicting response to medical castration.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Closed to new patient accrual. Open for followup purposes only.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8710 Status: Ongoing

Title: Trial of Cystectomy Alone Versus Neoadjuvant M-VAC + Cystectomy in Patients with Locally Advanced Bladder Cancer, Phase III.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian M. Thompson, MAJ, MC
Key Words: Cancer, Advanced Bladder	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	1
Total Number of Subjects Enrolled to Date:	2
Date of Periodic Review	18 Oct 93 Results Continue

Objective(s): 1) To compare the survival of those patients with locally advanced bladder cancer treated with cystectomy alone to those treated with M-VAC followed by cystectomy in a randomized Phase III neoadjuvant trial. 2) To quantify the "tumor downstaging" effect of neoadjuvant M-VAC in patients with locally advanced bladder cancer.

Technical Approach: All patients must have histologically proven diagnosis of T<sub>1</sub>-T<sub>4</sub>, N<sub>0</sub>, M<sub>0</sub> transitional cell carcinoma of the bladder without mixed histology. All patients must have adequate kidney, liver, and bone marrow function, a performance status of 0-1, and be judged potentially curable. Therapy will follow the schema outlined in the study protocol.

Progress: This trial is still open to patient accrual. A total of 131 patients have been entered on study. The accrual goal is 290.

Detail Summary Sheet

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Date: 15 Dec 93 Proj No: SWOG 8711 Status: Ongoing

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Title: A Study of Reproductive Function in Patients with Testicular Cancer.

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Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian M. Thompson, MAJ, MC
Key Words: Cancer, Testicular	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 18 Oct 93 Results Continue	

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Objective(s): 1. To evaluate the natural history of seminal fluid and hormonal parameters noted in Stage A testicular cancer patients treated by orchietomy alone.

2. To evaluate the effects of a) orchietomy plus platinum based combination chemotherapy or radiation therapy and b) retroperitoneal node dissection on the seminal fluid and hormonal parameters of Stage A, B, or C testicular cancer patients.

3. To estimate the median time to return to ejaculatory function following orchietomy and retroperitoneal node dissection.

4. To study the effect of testicular cancer on sexual/ reproductive functioning.

Technical Approach: Each patient must have histologically proven diagnosis of testis cancer for which he has undergone an orchietomy. Patients must be registered within three weeks of their surgery. Therapy will follow the schema outlined in the study protocol.

Progress: Study remains open for patient accrual.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8719 Status: Ongoing

Title: Evaluations of Didemnin B or Ifosfamide/Mesna in Endocrine Resistant Prostate Cancer and of Ifosfamide/Mesna in Patients without Prior Endocrine Manipulation. Phase II

Start Date FY 89	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian M. Thompson, MAJ, MC
Key Words: Cancer, Prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): To determine the response rate, response duration and toxicity of trimetrexate given on a daily X 5 schedule every three weeks to patients with hepatoma.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual. Open for followup purposes only.

Detail Summary Sheet

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Date: 15 Dec 93 Proj No: SWOG 8733 Status: Ongoing

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Title: Evaluation of Operable Bladder Cancer Patients with Pre-Operative Irradiation + 5-FU Alone, Phase II, a Pilot Study for Patients Ineligible for SWOG-8710.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian Thompson, MAJ, MC
Key Words: Cancer, Bladder	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 18 Oct 93 Results Continue	

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Objective(s): 1) Operable Patients: To evaluate the complete downstaging rate in patients with bladder cancer who are treated with pre-operative 5-FU/radiation. to assess the efficacy of treating patients with no histologic evidence of residual tumor following irradiation and 5-FU with additional irradiation and 5-FU without cystectomy. To assess the efficacy of treating patients who are not free of disease after initial treatment with 5-FU/radiation with radical cystectomy. 2) Inoperable Patients: To estimate the response rate of patients treated with 5-FU and radiation. To assess the qualitative and quantitative toxicities of this regimen in the treatment of bladder cancer.

Technical Approach: Patients must have primary or recurrent bladder cancer confined to the pelvis and no evidence of spread beyond the regional lymph nodes at or below the level of the bifurcation of the iliac vessels. Patients with prior inactive malignancies are eligible. Therapy will follow the schema outlined in the protocol.

Progress: Study continues for patient accrual.

**Detail Summary Sheet**

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Date: 15 Dec 93 Proj No: SWOG 8736 Status: Ongoing

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Title: Treatment of Localized Non-Hodgkin's Lymphoma: comparison of Chemotherapy (CHOP) to Chemotherapy plus Radiation Therapy.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Lymphoma, Non-Hodgkin's	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 5	
Date of Periodic Review 18 Oct 93 Results Continue	

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Objective(s): 1) To establish the complete response rate (CR%), CR duration, survival and toxicity of chemotherapy using Cyclophosphamide, Doxorubicin, Vincristine and Prednisone (CHOP) (eight cycles) versus CHOP (three cycles) plus radiation therapy in a cooperative group setting for patients with localized diffuse large cell lymphoma (DLC). 2) To determine if the difference in CR rates of combined treatment (less chemotherapy alone translates into longer survival with less toxicity. 3) To determine if subgroups (based on location, histology, age, stage) have significant prognostic importance with regard to CR%, time to progression, survival and toxicity. 4) To establish CR%, time to progression and survival for localized histologies other than diffuse large cell lymphoma.

Technical Approach: All patients must have biopsy proven Stage I or IE or non-bulky Stage II or IIE non-Hodgkin's lymphoma. Patients must have intermediate or high grade histology other than lymphoblastic lymphoma. No prior chemotherapy or radiation therapy is allowed. Patients with known AIDS syndrome or HIV associated complex are not eligible. Therapy will follow the schema outlined in the study protocol.

Progress: Two hundred and seventeen patients have been entered on this study. There are no major problems with the study. Accrual continues as expected. No fatal toxicities have been observed.

**Detail Summary Sheet**

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Date: 15 Dec 93 Proj No: SWOG 8737 Status: Ongoing

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Title: Phase III AZQ 24-Hour Infusion Versus BCNU for Adult High Grade Gliomas.

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Start Date FY 89	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Gliomas, high-grade	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 5	
Date of Periodic Review 19 Oct 92	Results Continue

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Objective(s): 1) To compare the activity of 24-hour infusion AZQ versus a BCNU control for adult, high grade, supratentorial gliomas. Primary endpoints for evaluation will be survival and time to progression. Secondary endpoints, when evaluable, will be partial and complete response rates as determined by contrast enhanced CT scan. Identification of a 50% increase in survival over control is sought. 2) To develop a data base on current surgical practices with protocol patients and to study further the prevalence and management of pulmonary toxicity from BCNU.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual. Open for followup purposes only.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8750 Status: Completed

Title: Pilot Study to Examine Cytogenetic Abnormalities in Patients with Acute Leukemia Ancillary.

Start Date FY 89	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Leukemia, Acute, Ancillary	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 18 Oct 93	Results Completed

Objective(s): 1) To develop the capability for group-wide cytogenetic studies in leukemia within the Southwest Oncology group with performance of studies at an institutional level followed by a central review of the data. 2) To organize a panel of expert cytogenetics within the Southwest Oncology Group that will form the core of the central cytogenetic review process. 3) To estimate the percentage of cases that are properly prepared and for which the central review confirms the local analysis. 4) To compare the cytogenetic abnormalities present in individual patients with acute leukemia registered on companion therapeutic protocols one this one year pilot period.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study is now completed.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8792 Status: Ongoing

Title: Phase III Study of Alfa-n1 (Wellferon™) as Adjuvant Treatment for Resectable Renal Cell Carcinoma.

Start Date FY 87	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian M. Thompson, MAJ, MC
Key Words: Carcinoma, renal cell	
Accumulative MEDCASE Cost:	Est Accumulative  OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): To assess in a controlled fashion the effectiveness of interferon alfa-n1 (Wellferon™) as a surgical adjuvant in patients with renal cell carcinoma.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Ongoing. This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8793 Status: Ongoing

Title: Randomized Phase III Evaluation of Hormonal Therapy versus Observation in Patients with Stage D1 Adenocarcinoma of the Prostate Following Pelvic Lymphadenectomy and Radical Prostatectomy.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian M. Thompson MAJ, MC
Key Words: Adenocarcinoma, Prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): 1) To determine the time to progression and survival, in patients with histologically confirmed Stage D1 prostate cancer following prostatectomy and pelvic lymphadenectomy treated immediately with hormonal therapy. 2) Determine whether the effects of early hormone therapy on local control of D1 prostate cancer.

Technical Approach: Patients must have histologically confirmed diagnosis of adenocarcinoma of the prostate (not including "endometroid" carcinoma). Patients must have pathologic D1 disease. Histological confirmation of pelvic node involvement is required for a patient to be considered to have Stage D1 disease. Confirmation must be obtained by formal pelvic node dissection.

Progress: Ongoing. This study is closed to new patient accrual open for followup purposes only.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8794 Status: Ongoing

Title: Treatment of Pathologic Stage C Carcinoma of the Prostate with Adjuvant Radiotherapy.

Start Date FY 89	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian M. Thompson, MAJ, MC
Key Words: Carcinoma, Prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 16	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): 1) To compare in a randomized study, the disease-free survival rates in completely resected patients with pathologic stage C (T3N0M0) carcinoma of the prostate assigned to be treated with adjuvant external beam radiotherapy to that in patients assigned to receive no adjuvant therapy. 2) To assess the qualitative and quantitative toxicities of patients with pathologic stage C (T3N0M0) carcinoma of the prostate when treated with external beam radiotherapy.

Technical Approach: Patients must have undergone radical prostatectomy and pelvic lymphadenectomy with a histologically proved diagnosis of pathologic stage C (T3N0M0) carcinoma of the prostate. Patients must be able to begin treatment within 16 weeks after radical prostatectomy. Therapy will follow the schema outlined in the protocol.

Progress: A total of 94 patients have been entered out of 588 required. The average accrual is somewhat less than initially projected. No undue toxicities have been reported so far.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8795 Status: Ongoing

Title: Randomized Prospective Comparison of Bacillus Calmette-Guerin and Mitomycin-C Therapy and Prophylaxis in Superficial Transitional Cell Carcinoma of the Bladder, with DNA Flow Cytometric Analysis, Phase III.

Start Date FY 89	Est Comp Date:		
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center		
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian M. Thompson, MAJ, MC		
Key Words: Carcinoma, Bladder Superficial, Transitional Cell			
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:		
Number of Subjects Enrolled During Reporting Period:	0		
Total Number of Subjects Enrolled to Date:	4		
Date of Periodic Review	18 Oct 93	Results	Continue

Objective(s): The overall objective of this protocol is to compare the efficacy and toxicity of two commonly used intravesical treatments for recurrent transitional cell carcinoma. The treatments to be evaluated are Mitomycin-C (MMC), and Tice substrain of Bacillus Calmette-Guerin (BCG).

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Ongoing. This study is closed to new patient accrual. Open for followup purposes only

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8805 Status: Ongoing

Title: Neadjuvant Cisplatin and VP-16 plus Concurrent Chest and Optional Brain Irradiation for Patients with Stage III Non-small Cell Lung Carcinoma, A Phase II Pilot.

Start Date FY 89	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, Lung Stage III, Non-Small Cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	1
Total Number of Subjects Enrolled to Date:	5
Date of Periodic Review	18 Oct 93 Results Continue

Objective(s): 1) To assess the feasibility and toxicity of treating patients with Stage III non-small cell lung cancer with cisplatin and VP-16 for two cycles, concurrent with a program of continuous, fractionated chest and optional whole brain irradiation, followed by surgical resection. 2) To assess the objective response rate, resectability rate, and proportion of patients free of microscopic residual disease after such an approach. 3) To assess whether immunocytochemical analysis and/or DNA analysis (ploidy, proliferative fraction) define subset(s) of patients who benefit from this combined modality approach, and to potentially assess the impact of chemoradiotherapy on the ploidy of the tumor.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8809 Status: Ongoing

Title: A Phase III Study of Alpha Interferon Consolidation Following Intensive Chemotherapy With ProMACE-MOPP (Day 1-8) in Patients With Low Grade Malignant Lymphomas.

Start Date FY 89	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Lymphomas, malignant, low grade	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	1
Total Number of Subjects Enrolled to Date:	7
Date of Periodic Review	18 Oct 93 Results Continue

Objective(s): 1) To compare the disease-free survival of patients with low grade malignant lymphoma who receive alpha interferon consolidation therapy after intensive induction with chemotherapy + radiation therapy, to those who receive induction therapy alone. 2) To determine the complete response rate, response duration and survival of low grade lymphoma patients treated with ProMACE-MOPP (Day 1-8). 3) To compare the toxicities of induction and induction plus consolidation therapy in this patient population.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Ongoing for patient accrual and followup purposes.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8810 Status: Completed

Title: Six courses of 5-Fluorouracil and Cis-platinum with Correlation of Clinical Cellular DNA Parameters in Patients with Advanced, Untreated and Unresectable Squamous Cell Carcinoma of the Head and Neck Phase III.

Start Date FY 88	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, Head and Neck	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 18 Oct 93	Results Completed

Objective(s): 1) Evaluate, following three and six courses of treatment the likelihood of increased numbers of patients achieving complete response rates when given three additional courses of the same regimen. 2) Evaluate the qualitative and quantitative toxicities of 5-fluorouracil and cisplatin following three and six courses of treatment.

3) Evaluate by serial biopsy and flow cytometry the correlation of the cellular DNA parameters of degree of aneuploidy (DNA index) and proliferative activity (SPF) with patient clinical characteristics, tumor morphology, cytotoxic response, disease free interval and survival.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study completed. There have been no patients entered on study during this reporting period.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8814 Status: Ongoing

Title: Phase III Comparison of Adjuvant Chemoendocrine Therapy with CAF and Concurrent or Delayed Tamoxifen to Tamoxifen Alone in Postmenopausal Patients with Involved Axillary Lymph Nodes and Positive Receptors.

Start Date FY 89	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Breast, Receptor Positive	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 11	
Date of Periodic Review 19 Oct 92	Results Continue

Objective(s): 1) To compare disease-free survival and overall survival of postmenopausal primary breast cancer patients with involved axillary nodes and positive estrogen and/or progesterone receptors treated with standard adjuvant therapy with long-term tamoxifen, or with chemoendocrine therapy with CAF, followed by long-term tamoxifen, or with concurrent chemoendocrine therapy with tamoxifen and CAF. 2) To compare the relative toxicity of the three therapies.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study continues for patient accrual and followup.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8816 Status: Completed

Title: Study of 13-cis Retinoic Acid (Accutane) Plus rIFN-alpha A (Roferon-A) in Mycosis Fungoides, Phase II.

Start Date FY 89	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Fungoides, Mycosis, Phase II	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 18 Oct 93	Results Completed

Objective(s): 1) To evaluate the response rate of mycosis fungoides (cutaneous T-cell lymphoma) treated with the drug combination of 13-cis Retinoic Acid (Accutane) plus rIFN-alpha A (Roferon-A). 2) To assess the qualitative and quantitative toxicities of the regimen in a Phase II study.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: No new patients have been entered into study during this reporting period.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8819 Status: Ongoing

Title: Central Lymphoma Repository Tissue Procurement Protocol.

Start Date FY 89	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Lymphoma, central Tissue, repository	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 18 Oct 93 Results Continue	

Objective(s): 1) To acquire fresh snap-frozen lymphoma tissue to establish a central lymphoma tissue repository. 2) To establish a standard set of procedures for routine acquisition, banking, and study of lymphoma tissues within the cooperative group. 3) To use repository tissue to establish clinical correlations via presently activated phenotyping studies and future projected molecular studies assessing specimen DNA and RNA status. 4) To determine if pretreatment phenotype or genotype predict patient outcome with respect to complete response rate, time to progression, and survival using prospective trial designs.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study continues for data accrual.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8822 Status: Completed

Title: A Phase II Study of Continuous Infusion Recombinant Interleukin-2 in Patients with Malignant Lymphoma.

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Lymphoma, Malignant	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 18 Oct 93	Results Completed

Objective(s): 1) To evaluate the response rate of malignant lymphomas to treatment with recombinant human interleukin-2 (rIL-2) given by continuous infusion. 2) To evaluate the toxicity of the treatment program used.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study completed. There are no patients enrolled on study.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8828 Status: Completed

Title: A Phase II Trial of Carboplatin (CBDCA) in Relapsed or Refractory Acute Myeloid leukemia.

Start Date FY 90	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Leukemia, Acute Myeloid, Refractory	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 18 Oct 93	Results Completed

Objective(s): 1) To evaluate the complete remission rate of carboplatin (CBDCA) in patients with relapsed or refractory acute myeloid leukemia (AML). 2) To assess the qualitative and quantitative toxicities in patients with relapsed AML treated with carboplatin. 3) To identify the pattern of treatment failure by the criteria of Priesler.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There have been no patients entered on study during this reporting period.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8833 Status: Ongoing

Title: Phase II Investigation of Chlorambucil and Fludarabine Monophosphate in Relapsed or Refractory Chronic Lymphocytic Leukemia.

Start Date FY 89	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Leukemia, Chronic Lymphocytic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): To estimate the maximum tolerated dose (MTD) of Fludarabine monophosphate (FAMP) when given in combination with chlorambucil for patients with relapsed or refractory chronic lymphocytic leukemia (CLL).

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8842 Status: Completed

Title: Dihydroxyazacytidine in Malignant Mesothelioma, Phase II.

Start Date FY 90	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Mesothelioma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 18 Oct 93	Results Completed

Objective(s): 1) To assess the response rate and survival of patients with unresectable malignant mesothelioma treated with Dihydroxyazacytidine (DHAC, NSC-264880). 2) To further evaluate the toxicity of DHAC given by continuous infusion. 3) To prospectively evaluate the use of CA-125 as a tumor marker in mesothelioma.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There have been no patients entered into study during this reporting period.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8851 Status: Ongoing

Title: Phase III Comparison of Combination Chemotherapy (CAF) and Chemohormonal Therapy (CAF + Zoladex or CAF + Zoladex + Tamoxifen) in Premenopausal Women with Axillary Node-Positive, Receptor-Positive Breast Cancer --Intergroup.

Start Date FY 89	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Breast, Receptor-Positive	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): 1) To compare the recurrence rates, disease-free intervals (DFI), and hormone-receptor-positive survival for premenopausal women with axillary lymph node-positive breast cancer given adjuvant therapy with chemotherapy (CAF) alone or chemotherapy (CAF) followed by Zoladex (Z) or chemotherapy (CAF) followed by Zoladex plus Tamoxifen (Z + T). We will compare CAF with CAF + Z and CAF + Z with CAF + Z + T. 2) To compare the relative toxicities of these 3 regimens. 3) To assess the effect of CAF, CAF + Z, and CAF + Z + T on hormone levels (LH, FSH, and estradiol) in premenopausal women treated with these adjuvant therapies.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study continues for patient enrollment and data accrual.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8854 Status: Ongoing

Title: Prognostic Value of Cytometry Measurements of Breast Cancer DNA from Postmenopausal Patients with Involved Nodes and Receptor Positive Tumors: A Companion Protocol to SWOG 8814.

Start Date FY 89	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Breast	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 5	
Date of Periodic Review 19 Oct 92	Results Continue

Objective(s): 1) To determine if ploidy analysis of breast cancer by routine clinical flow cytometry (FCM) technique can predict response to therapy and survival of patients registered to SWOG-8814. 2) To determine if ploidy analysis by image processing technique more accurately predicts patient response to therapy and survival than ploidy analysis by FCM.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Patients continue to be registered and the trial remains open.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8855 Status: Ongoing

Title: A Flow Cytometry Companion Protocol to All Southwest Oncology Group Head and Neck Cancer Protocols Utilizing Chemotherapy as Initial Treatment.

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Head and Neck	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 18 Oct 93 Results Continue	

Objective(s):

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data at this time.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8857 Status: Completed

Title: Alternating Cisplatin/VP-16 with Continuous CAV and Consolidation Chemotherapy for Extensive Small Cell Lung Cancer with PCI for Complete Responders.

Start Date FY 90	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Small cell lung cancer, extensive	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 6	
Date of Periodic Review 18 Oct 93	Results Completed

Objective(s): 1) To assess response rate (especially rate of CR) and toxicity of a "dose intensive" approach to induction chemotherapy in which cisplatin/VP-16 is alternated with cyclophosphamide, adriamycin and vincristine; consolidation therapy will be given to responders with one cycle of each induction regimen, coupled with prophylactic brain irradiation in CR patients. 2) To measure survival in patients so treated.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study closed to patient accrual.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8892 Status: Ongoing

Title: A Study of Radiotherapy With or Without Concurrent Cisplatin in Patients with Nasopharyngeal Cancer, Phase III

Start Date FY 89	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Nasopharyngeal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): 1) To compare the complete response rate, time to treatment failure, overall survival and pattern of recurrence. 2) To assess the qualitative and quantitative toxicities.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Accrual to this intergroup study has been poor but has begun to increase recently. Twenty-three patients have been registered since the study was activated in May 1989. Only two patients have been evaluated for response and both have data from only the first response assessment time. Both achieved a PR at their first response assessment and further follow-up data is forthcoming to confirm the responses. Three of eight patients evaluated have had Grade 4 toxicity. An article recently printed in the JCO on the RTOG pilot results should generate interest among investigators. The study was amended to base dose modifications on granulocytes.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8894 Status: Ongoing

Title: A Comparison of Bilateral Orchiectomy with or without Flutamide for the Treatment of Patients with Histologically Confirmed Stage D<sub>2</sub> Prostate Cancer.

Start Date FY 90	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian M. Thompson, MAJ, MC
Key Words: Cancer, prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 7	
Total Number of Subjects Enrolled to Date: 28	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): To compare bilateral orchiectomy + flutamide versus bilateral orchiectomy alone according to: 1) Survival, 2) Progression free survival, 3) Qualitative and quantitative toxicities.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: No major toxicities have been reported so far. The study continues to progress without any major problems. The study continues to accrue patients.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8895 Status: Ongoing

Title: Phase III Study of the role of Cricopharyngeal Myotomy in the Treatment of Dysphagia following Major Head and Neck Surgery.

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Head and Neck	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): 1) The objective of this study is to test the concept that cricopharyngeal myotomy performed in conjunction with the resection of a tumor involving the base of tongue or supraglottic larynx or hypopharynx will increase the frequency of patients with normal swallowing function at six months.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study continues to enroll patients for data accrual.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8896 Status: Completed

Title: Phase III Protocol for Surgical Adjuvant therapy of Rectal Carcinoma: A Controlled Evaluation of A: Protracted Infusion 5-Fluorouracil as a Radiation Enhancer and B: 5-FU Plus Methyl-CCNU Chemotherapy.

Start Date FY 89	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, rectal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 18 Oct 93	Results Completed

Objective(s): 1) To compare the local recurrence rates, rates of distant metastasis, disease-free survival, and overall survival in patients having potentially curative resections of modified Astler Coller <sub>B2</sub> and C<sub>1,3</sub> rectal carcinoma treated with sequential chemotherapy and radiotherapy using 5-FU as a radiation enhancer given either by simple IV bolus administration or by Protracted Venous Infusion (PVI) concomitant with radiation therapy. 2) To compare the same study endpoints for the same group of patients who either receive Methyl-CCNU as a component of the systemic therapy regimen or do not receive Methyl-CCNU as a component of the systemic chemotherapy regimen.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study completed. The results of the study are not available at this time.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8897 Status: Ongoing

Title: Phase III Comparison of Adjuvant Chemotherapy with or without Endocrine Therapy in High-Risk, Node Negative Breast Cancer Patients, and a Natural History Follow-up Study in Low-Risk, Node Negative Patients (Intergroup).

Start Date FY 89	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Breast, Node Negative	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 34	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): 1) To compare disease-free survival (DFS) and overall survival(s) of high risk primary breast cancer patients with negative axillary lymph nodes treated with standard adjuvant chemotherapy with CMF for six cycles or with chemotherapy using CAF for six cycles. 2) To assess the value of the addition of tamoxifen for five years compared to no tamoxifen in these patients. 3) To compare the relative toxicity of the therapies. 4) To assess the prognostic significance of DNA flow cytometry in patients with small, occult invasive breast cancer treated by local therapy only. 5) To evaluate the disease free survival and survival of low risk invasive breast cancer determined by receptor status, tumor size and % of S phase treated by local therapy only.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Ongoing. This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8899 Status: Ongoing

Title: A Prospectively Randomized Trial of Low-Dose Leucovorin Plus 5-FU, High-Dose Leucovorin Plus 5-FU, or Low-Dose Leucovorin Plus 5-FU Plus Levamisole Following Curative Resection in Selected Patients with Duke's B or C Colon Cancer.

Start Date FY 89	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Colon, Duke's B/C	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 19	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): 1) To independently assess the effectiveness of 5-FU + low-dose Leucovorin, 5-FU + high dose Leucovorin 5-FU + Levamisole and 5-FU + low-dose Leucovorin + Levamisole as surgical adjuvant therapy for resectable colon cancer

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Ongoing. This study is closed to new patient accrual open for followup purposes only.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8901 Status: Completed

Title: Clinical Trial of the Most Active Drugs Selected by Clonogenic Assay to be Administered by the Intrahepatic Arterial Route for Colorectal Cancer Metastatic to the Liver.

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Colorectal, Metastatic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 18 Oct 93	Results Completed

Objective(s): 1) To assess, in the setting of a phase II clinical trial, the efficacy of the approach of selecting anticancer drugs based on the results of the human tumor clonogenic assay for intrahepatic arterial administration in patients with colorectal cancer metastatic in the liver. 2) To assess the toxicities of anticancer drugs chosen by this approach.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There were no patients enrolled during this reporting period. Study completed.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8905 Status: Completed

Title: Phase II/III Study of Fluorouracil (5FU) and its Modulation in Advanced Colorectal Cancer.

Start Date FY 89	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Colorectal, Advanced	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 5	
Date of Periodic Review 19 Oct 92	Results Completed

Objective(s): 1) To determine and compare response rates and toxicities of 5-fluorouracil given by different schedules and/or with biochemical modulators to patients with advanced colorectal cancer. 2) To compare patient survival on the different 5-FU regimens.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study completed. There were no patients enrolled during this reporting period.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8910 Status: Ongoing

Title: Evaluation of Low Dose Continuous 5-Fluorouracil (5-FU) and Weekly Cis-Platinum (CDDP) in Advanced Adenocarcinoma of the Stomach.

Start Date FY 90	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Stomach, adenocarcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 18 Oct 93	Results Complete

Objective(s): 1) To evaluate response to low dose continuous 5-FU and weekly cis-platinum in patients with advanced adenocarcinoma of the stomach. 2) To assess the qualitative and quantitative toxicities of this regimen.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study remains open for patient accrual.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8911 Status: Ongoing

Title: Evaluation of Piroxantrone in Refractory Carcinoma of the Breast, Phase II.

Start Date FY 90	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Breast, carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 18 Oct 93 Results Continue	

Objective(s): 1) To evaluate the response rate of refractory carcinoma of the breast to treatment with piroxantrone. 2) To evaluate the toxicities of piroxantrone in this patient population.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8913 Status: Ongoing

Title: Phase II Trial of Merbarone in Disseminated Malignant Melanoma.

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Melanoma, Disseminated	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review <u>18 Oct 93</u> Results Continue	

Objective(s): 1) To evaluate the response rate of disseminated malignant melanoma treated with merbarone. 2) To assess the qualitative and quantitative toxicities of merbarone administered in a Phase II study.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study remains ongoing for patient accrual.

Detail Summary Sheet

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Date: 15 Dec 93 Proj No: SWOG 8917 Status: Ongoing

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Title: 5-Fluorouracil, Leucovorin and Roferon-A in Advanced Colorectal Cancer, Phase II Pilot.

Start Date FY 90	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, colorectal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 8	
Date of Periodic Review <u>18 Oct 93</u> Results <u>Continue</u>	

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Objective(s): 1) To evaluate the likelihood of response in order to assess whether this regimen should be advanced to further study. 2) To evaluate the qualitative and quantitative toxicities of this regimen.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study ongoing. This study is closed to new patient accrual, open for followup purposes only.

**Detail Summary Sheet**

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Date: 15 Dec 93    Proj No: SWOG 8921    Status: Ongoing

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Title: Phase II Trials of Cyclophosphamide, IL-2, DTIC/IL-2 and DTIC/Cisplatin/ Tamoxifen in Stage IV Melanoma.

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Start Date    FY 90	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Melanoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	2
Date of Periodic Review	18 Oct 93    Results    Continue

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Objective(s): 1) To evaluate the response rates in patients with disseminated malignant melanoma treated with one of three regimens: cyclophosphamide (CY) and IL-2; dacarbazine (DTIC) and IL-2; or DTIC, cisplatin (CDDP) and tamoxifen (TAM). 2) To assess the qualitative and quantitative toxicities associated with each of the three regimens.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This trial remains open for patient accrual.

**Detail Summary Sheet**

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Date: 15 Dec 93 Proj No: SWOG 8925 Status: Ongoing

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Title: Evaluations of Cisplatin + VP-16 Followed by Mitotane at Progression if No Prior Mitotane or Cisplatin + BP-16 Only if Prior Treatment with Mitotane in Advanced and Metastatic Adrenal Cortical Carcinoma.

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Start Date FY 89	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, Metastatic Adrenal Cortical	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 18 Oct 93	Results Continue

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Objective(s): 1) To evaluate the response and response duration of patients with:

- adrenocortical carcinoma treated with combination chemotherapy consisting of cisplatin and etoposide, and  
- of those who receive mitotane after progression on the above chemotherapy (if no prior treatment with mitotane). 2) To evaluate the qualitative and quantitative toxicities of these therapies. 3) To evaluate and compare tumor morphology of patients with this rare tumor.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: There is no new reportable data available at this time.

**Detail Summary Sheet**

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**Date: 15 Dec 93      Proj No: SWOG 8929      Status: Completed**

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**Title: Evaluation of Merbarone in Patients with Advanced Renal Cell Carcinoma.**

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<b>Start Date</b> FY 90	<b>Est Comp Date:</b>
<b>Principal Investigator:</b> Timothy J. O'Rourke, LTC, MC	<b>Facility:</b> Brooke Army Medical Center
<b>Dept/Svc:</b> Department of Medicine/Oncology	<b>Associate Investigators:</b> Ian M. Thompson, MAJ, MC
<b>Key Words:</b> Renal cell, carcinoma	
<b>Accumulative MEDCASE</b>	<b>Est Accumulative</b>
<b>Cost:</b>	<b>OMA Cost:</b>
<b>Number of Subjects Enrolled During Reporting Period:</b> 0	
<b>Total Number of Subjects Enrolled to Date:</b> 2	
<b>Date of Periodic Review</b> <u>19 Oct 92</u> <b>Results</b> <u>Continue</u>	

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**Objective(s):** 1) To evaluate the response rate of advanced renal cell metastatic or recurrent, treated with Merbarone. 2) To assess the qualitative and quantitative toxicities of merbarone administered in a Phase II study.

**Technical Approach:** Therapy will follow the schema outlined in the protocol.

**Progress:** Study completed. There is no reportable data at this time.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8931 Status: Ongoing

Title: Phase III Comparison of Cyclophosphamide, Doxorubicin, and 5-Fluorouracil (CAF) and a 16-Week Multi-Drug Regimen as Adjuvant Therapy for Patients with Hormone Receptor Negative, Node-Positive Breast Cancer.

Start Date FY 90	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Breast, cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	2
Date of Periodic Review	18 Oct 93 Results Continue

Objective(s): 1) To compare disease-free and overall survival in node positive receptor negative breast cancer patients receiving adjuvant CAF or a 16 week multi-drug chemotherapy regimen. 2) To compare toxicities of adjuvant CAF and a 16 week multi-drug regimen.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Ongoing. This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8942 Status: Ongoing

Title: High Dose Etoposide, Cyclophosphamide and Either Fractionated Total Body Irradiation or Carmustine Combined with Autologous Bone Marrow Rescue for Refractory or Relapsed Non-Hodgkin's Lymphoma.

Start Date FY 90	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Lymphoma, non-hodgkin's	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 18 Oct 93 Results Continue	

Objective(s): 1) To evaluate in a group-wide setting the complete response rate and survival of patients with either "sensitive" or "resistant" relapsed or refractory Non-Hodgkin's lymphoma treated with high dose VP-16, cyclophosphamide, and fractionated total body irradiation or VP-16, cyclophosphamide and BCNU (for patients receiving any prior mediastinal RT) combined with an autologous bone marrow transplant. 2) To assess the non-hematopoietic toxicities of these regimens.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study ongoing for patient accrual.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8947 Status: Ongoing

Title: Central Lymphoma Serum Repository Protocol.

Start Date FY 90	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Lymphoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): 1) To establish a central lymphoma serum repository that will serve as a resource to provide specimens for current and future scientific studies. 2) To utilize the Southwest Oncology Group clinical database to perform clinicopathologic correlations with the results of those studies.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study ongoing for data accrual.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8949 Status: Ongoing

Title: A Randomized Comparison of Nephrectomy Followed by Intron-A vs Intron-A Alone in Patients with Advanced Renal Cell Carcinoma

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian M. Thompson, MAJ, MC
Key Words: Carcinoma, Advanced Renal Cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 18 Oct 93 Results Continue	

Objective(s): 1) To evaluate and compare the survival and response rates of patients with metastatic renal cell carcinoma receiving nephrectomy followed by Interferon Alpha-2b (Intron-A) vs. Interferon Alpha-2b (Intron-A) alone. 2) To evaluate morbidity and mortality associated with adjuvant nephrectomy in metastatic renal cell carcinoma.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study ongoing. No reportable data is available at this time.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8952 Status: Ongoing

Title: Treatment of Advanced Hodgkin's Disease - A Randomized Phase III Study Comparing ABVD vs MOPP/ABV Hybrid.

Start Date FY 90	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Advanced hodgkins	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 18 Oct 93 Results Continue	

Objective(s): 1) To compare ABVD to the MOPP/ABV hybrid as therapy for patients with advanced Hodgkin's disease in terms of complete response rates, disease-free survival, failure-free survival and both immediate and long-term toxicities. 2) To compare the rate of drug delivery of the anti-neoplastic agents, especially the comparative dose rate of ABV in the two treatment groups. 3) To examine the prognostic importance of time to response, performance status, age, presence of bulky disease, C-reactive protein, erythrocyte sedimentation rate, and prior radiotherapy on survival.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study ongoing. No reportable data at this time.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8954 Status: Ongoing

Title: Evaluation of the L-17M Protocol in the Management of Patients with Lymphoblastic Lymphoma, Phase II, Pilot.

Start Date FY 90	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Lymphoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): 1) To assess the response rate and response duration of lymphoblastic lymphoma treated with the L-17M protocol. 2) To assess the qualitative and quantitative toxicities of the L-17M protocol administered in a Phase II study. 3) To assess the immunophenotypic characteristics of adult lymphoblastic lymphoma.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study ongoing. Study remains open for data accrual.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8955 Status: Ongoing

Title: Treatment of Stage D, Hormone Refractory Carcinoma of the Prostate with 5 Fluorouracil and Roferon-A, Phase I.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian M. Thompson MD
Key Words: Refractory carcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): 1) To evaluate the likelihood of response of hormone refractory, metastatic carcinoma of the prostate treated with 5-FU and Roferon-A in order to assess whether this regimen should be advanced to further studies. 2) To assess the qualitative and quantitative toxicities of this regimen administered in a phase II study.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study remains open. There is no reportable data available.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8956 Status: Completed

Title: A Phase II Study of Cisplatin and 5-FU Infusion for Treatment of Advanced and /or Recurrent Metastatic Carcinoma of the Urinary Bladder.

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian M. Thompson, MAJ, MC
Key Words: Carcinoma, Bladder	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 18 Oct 93 Results Completed	

Objective(s): 1) To assess efficacy and feasibility of utilizing Cisplatin (CDDP) and 5-Fluorouracil infusion (5-FU) in patients with advanced and/or recurrent carcinoma of the urinary bladder. 2) To evaluate the toxicity of Cisplatin + 5-FU in this group of patients.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8990 Status: Ongoing

Title: Combined Modality Treatment for Resectable Metastatic Colorectal Carcinoma to the Liver: Surgical Resection of Hepatic Metastases in Combination with Continuous Infusion of Chemotherapy.

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, Colorectal Metastatic to liver	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): 1) To study the incidence of recurrence and time to recurrence in patients with 1-3 hepatic metastases treated with resection alone versus resection and continuous infusion of 5-FU into the systemic venous system and FUDR into the hepatic artery.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8991 Status: Completed

Title: A phase III Study of Cisplatin plus Etoposide Combined with Standard Fractionation Thoracic Radiotherapy vs Cisplatin Plus Etoposide Combined with Multiple Daily Fractionated Thoracic Radiotherapy for Limited Stage Small Cell Lung Cancer.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Limited Stage Small Cell Lung	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 18 Oct 93	Results Completed

Objective(s): 1) To compare the median and long-term (i.e., > 2 year) survivals of limited stage SCLC patients receiving Cisplatin/Etoposide induction chemotherapy combined with concurrent thoracic radiotherapy given in either a standard, once daily fractionation scheme or a twice daily fractionation scheme. 2) To compare intrathoracic, within radiation portal and distant failure rates of these regimens. 3) To compare the toxicities of standard fraction, concurrent thoracic radiotherapy with the toxicities of small, multiple daily fraction concurrent thoracic radiotherapy. 4) To determine the clinical significance of variant morphology small cell carcinoma of the lung.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8993 Status: Ongoing

Title: Phase II Study of High Dose Melphalan with Hemopoietic Stem Cell Support and GM-CSF in Refractory Multiple Myeloma.

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Myeloma, Multiple	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): 1) To evaluate therapeutic efficacy and toxicity of high dose melphalan (HDM 200mg/M<sup>2</sup>) in patients with multiple myeloma (MM) resistant to VAD and alkylating agents followed by autologous hemopoietic stem cell support (marrow and/or blood) and GM-CSF administration. 2) To assess the feasibility of measuring multi-drug resistance in this group of patients. 3) To determine the feasibility of conducting such high dose therapy in a multi-institutional setting such as SWOG as a prelude to future trials for patients earlier in the disease course.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 8994 Status: Ongoing

Title: Evaluation of Quality of Life in Patients with Stage C Adenocarcinoma of the Prostate Enrolled on SWOG 8794.

Start Date FY 90	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian M. Thompson, MAJ, MC
Key Words: Prostate, adenocarcinoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 11	
Date of Periodic Review 18 Oct 93 Results Continue	

Objective(s): 1) To compare these primary aspects of quality of life, according to treatment assignment: 1.11) Treatment specific symptoms; 1.12) Physical functioning; 1.13) Emotional functioning.

2) To compare three secondary quality of life variables, according to treatment assignment: 1.21) General symptoms; 1.22) Global perception of quality of life; 1.23) Social functioning.

3) The comparison of quality of life measurements between treatment arms will complement the analysis of survival data for patients registered to SWOG-8794 and become a critical consideration if no difference is demonstrated in survival between the treatment arms.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data at this time.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9000 Status: Ongoing

Title: Biomarkers of Colorectal Cancer Prognosis.

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Colorectal Cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 18 Oct 93 Results Continue	

Objective(s): 1) To evaluate if aneuploidy in Dukes B or C colon cancers as determined by flow cytometric analysis of DNA content has independent prognostic significance for survival or disease free survival in patients enrolled on SWOG-8591. 2) To evaluate if aneuploidy in colon cancers is predictive of patients who benefitted from adjuvant therapy with levamisole or 5-FU plus levamisole by increased survival or disease free survival in SWOG-8591.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 24 Feb 94 Proj No: SWOG 9003 Status: Ongoing

Title: Fludarabine for Waldenstrom's Macroglobulinemia (WM): A Phase II Pilot Study for Untreated and Previously Treated Patients

Start Date	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results Continue

Objective(s): 1) To estimate response rates and survival in patients with Waldenstrom's Macroglobulinemia (WM) receiving fludarabine, with stratification according to whether they have had prior therapy. 2) To define prognostic factors that may relate to response, time to progression and overall survival, separately for newly diagnosed and previously treated patients. 3) To estimate the associated hematologic and non-hematologic toxicities.

Technical Approach: As outlined in the protocol schema.

Progress: This is a new study. There is no reportable data.

Detail Summary Sheet

Date: 24 Feb 94 Proj No: SWOG 9005 Status: Ongoing

Title: Double Blind Randomized Trial of the Anti-Progestational Agent Mifepristone in the Treatment of Unresectable Meningioma, Phase III

Start Date	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results Continue

Objective(s): 1) To compare daily oral mifepristone vs placebo with respect to time to treatment failure in patients with unresectable meningioma. 2) To further evaluate the tolerance of long term oral mifepristone.

Technical Approach: As outlined in the protocol schema.

Progress: There is a new study. There is no reportable data.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9007 Status: Ongoing

Title: Cytogenetic Studies in Leukemia Patients, Ancillary.

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Leukemia	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 4	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): 1) To estimate the frequencies and prognostic significance of cytogenetic abnormalities in marrow or blood cells of leukemia patients prior to treatment on Southwest Oncology Group protocols and at various times in the course of their treatment. 2) To estimate correlations between the presence of cytogenetic features and of clinical, pathophysiological, cellular, or molecular characteristics in these patients. 3) To provide quality control for all Southwest Oncology Group cytogenetic data.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9008 Status: Ongoing

Title: Trial of Adjuvant Chemoirradiation After Gastric Resection for Adenocarcinoma.

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Adenocarcinoma, Gastric	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): 1) A comparison of overall and disease free survival between patients being treated with surgical resection only and those being treated with surgery plus adjuvant therapy. 2) A comparison of incidence and patterns of disease failure between surgery and surgery plus adjuvant therapy treated patients. 3) An assessment of patient tolerance of upper abdominal chemoirradiation after gastric resection.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9009 Status: Completed

Title: Pilot Study for Analysis of Lymphocyte Subsets and Natural Killer Activity after Treatment with Levamisole.

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Colon	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 18 Oct 93	Results Completed

Objective(s): 1) Describe the effect of levamisole on lymphocyte subsets in the peripheral blood over time in patients receiving adjuvant levamisole. 2) Describe the effect of levamisole on peripheral blood "natural killer" cytotoxicity over time in patients receiving adjuvant levamisole.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9011 Status: Ongoing

Title: High Dose Etoposide, Cyclophosphamide, and Either Fractionated Total Body Irradiation or Carmustine Combined with Autologous Bone Marrow Rescue for Refractory or Relapsed Hodgkin's Disease.

Start Date FY 90	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Bone marrow transplant, hodgkins disease	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 3	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): 1) To evaluate in a group-wide setting the complete response rate and survival of patients with either "sensitive" or "resistant" relapsed or refractory Hodgkin's disease treated with high dose VP-16, cyclophosphamide, and fractionated total body irradiation or VP-16, cyclophosphamide and BCNU (for patients receiving any prior mediastinal RT) combined with an autologous bone marrow transplant.

2) To assess the non-hematopoietic toxicities of these regimens in this patient population.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study remains ongoing. No fatal toxicities have been reported.

**Detail Summary Sheet**

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Date: 15 Dec 93    Proj No: SWOG 9013    Status: Ongoing

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Title: A Prospective Randomized Comparison of Combined Modality Therapy for Squamous Carcinoma of the Esophagus: Chemotherapy Plus Surgery vs Surgery alone for Patients with Local Regional Disease, Phase III-Intergroup.

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Start Date FY 90	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Squamous carcinoma, esophagus	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review    18 Oct 93    Results    Continue	

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Objective(s): 1) To compare, using a prospective controlled randomized study design, the outcomes of therapy of surgery alone, vs pre- and post- operative chemotherapy and surgery for patients with local regional esophageal cancer. Outcome is defined as survival and relapse pattern. 2) To assess the toxicities of a multimodality approach to esophageal carcinoma involving systemic chemotherapy and surgery. The toxicities of surgical resection, as initial therapy or following chemotherapy will be assessed as operative morbidity and mortality. 3) To compare the local and distant control rates with the two approaches and to define the pattern of failure. 4) To compare the impact on overall and disease free survival of multimodality therapy with surgery alone.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9015 Status: Ongoing

Title: A Randomized Trial of Pre- and Post- operative Chemotherapy Compared to Surgery Alone for Patients with Operable Non-Small Cell Carcinoma of the Lung, Phase III.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: cancer, non-small cell lung	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): 1) To compare the survival experience of patients with clinical stages T2N1, T1N1, T2N0, T3N0, and T3N1 NSCLC (mediastinoscopy negative) (Clinical stages Ib, II, IIIa) treated with either surgical resection alone (control) or a regimen of pre- and post-operative chemotherapy (experimental arm). 2) To estimate the response rate to pre-operative chemotherapy. 3) To test the association between response to pre-operative chemotherapy and survival of those patients who receive chemotherapy. 4) To estimate the toxicity, including operative complications, of combined pre- and post-operative chemotherapy.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study remains ongoing. There is no reportable data available.

**Detail Summary Sheet**

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Date: 15 Dec 93 Proj No: SWOG 9016 Status: Ongoing

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Title: Study of External Brain Irradiation and Cisplatin/BCNU Followed by BCNU for the Treatment of Primary Malignant Brain Tumors.

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Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Tumors, Brain	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 18 Oct 93	Results Continue

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**Objective(s):** The objectives of this study are to determine whether this regimen (radiation therapy + BCNU/cisplatin) can be given safely in a cooperative group setting and to demonstrate that adequate accrual can be achieved with this regimen. Other goals are: estimation of response and disease stabilization rates, and estimation of the probability of one year survival.

**Technical Approach:** The therapy will follow the schema outlined in the protocol.

**Progress:** There is no reportable data available at this time.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9019 Status: Ongoing

Title: A Phase III, Randomized, Prospective Comparison Between Chemotherapy Plus Radiotherapy Together with Surgery for Selected Stage IIIa (Positive Mediastinal Nodes) and Selected Stage IIIb (No Malignant Effusion) Non-Small Cell Lung Cancer.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 2	
Total Number of Subjects Enrolled to Date: 2	
Date of Periodic Review 18 Oct 93	Results Continue

Objective(s): 1) Assess whether concurrent chemotherapy and radiotherapy followed by surgical resection results in a significant improvement in progression-free, overall, and long-term survival compared to the same chemotherapy plus standard radiotherapy alone for patients with stage IIIa (N2-positive) and selected IIIb non-small cell lung cancer. 2) Evaluate the patterns of local and distant failure for patients enrolled in each arm of the study, in order to assess the impact of the therapy on local control and distant metastases.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: Study remains ongoing. There is no reportable data available.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9021 Status: Ongoing

Title: Post-Operative Radiotherapy for Single Brain Metastases, Phase II.

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Metastases	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review <u>18 Oct 93</u> Results Continue	

Objective(s): 1) To evaluate the effectiveness of whole brain radiation therapy given after complete resection of single brain metastasis from systemic cancer. 2) To compare complete surgical resection plus postoperative whole brain radiation therapy to complete resection alone, with respect to survival, site of recurrence, cause of death, and quality of life. 3) To evaluate the use of Quality of Life Questionnaire specific for CNS malignancies.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9024 Status: Ongoing

Title: A Pilot Study of Combined Modality Therapy in T3, 4; No, Mo Adenocarcinoma of the Prostate, Phase II.

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian M. Thompson, MAJ, MC
Key Words: Aden. carcinoma, Prostate	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 7	
Total Number of Subjects Enrolled to Date: 5	
Date of Periodic Review 19 Oct 92	Results Continue

Objective(s): 1) To evaluate the likelihood of complete response of T3, T4; NO, MO prostate cancer to prolonged venous infusion of 5-fluorouracil in combination with external beam radiation therapy. 2) To evaluate the safety and toxicity of pelvic irradiation in combination with prolonged venous infusion of 5-fluorouracil at a dose of 200mg/m2/day.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9028 Status: Ongoing

Title: A Phase III Randomized Trial of Combination Therapy for Multiple Myeloma Comparison of (1) VAD to VAD/Verapamil/Quinine for Induction with Crossover to VAD/Verapamil/Quinine for VAD Induction Failures; (2) Alpha-2B Interferon or Alpha-2B Interferon Plus Prednisone for Remission Maintenance.

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Myeloma, Multiple	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 19 Oct 92	Results Continue

Objective(s): 1) To compare the effectiveness of the VAD chemotherapy regimen when administered alone or in combination with chemosensitizers (verapamil/quinine) intended to block the emergence of multidrug resistance during remission induction in previously untreated patients with multiple myeloma.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

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Date: 15 Dec 93 Proj No: SWOG 9030 Status: Ongoing

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Title: Phase II Study of High Dose Ara-C/Mitoxantrone For the Treatment of Relapsed/Refractory Acute Lymphocytic Leukemia.

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Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Lymphocytic Leukemia
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	1
Total Number of Subjects Enrolled to Date:	1
Date of Periodic Review	19 Oct 92 Results Continue

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Objective(s): 1) To assess the complete response rate achieved in adult patients with relapsed or refractory ALL using the combination of high-dose Ara-C with mitoxantrone. 2) To evaluate the toxicities associated with this induction regimen.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This is a new study there is no reportable data available.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9031 Status: Ongoing

Title: A Double Blind Placebo Controlled Trial of Daunomycin and Cytosine Arabinoside With or Without rhG-CSF in Elderly Patients With Acute Myeloid Leukemia, Phase III.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Acute myeloid Leukemia
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 19 Oct 92 Results Continue	

Objective(s): 1) To compare the complete response rates and durations of survival in patients aged 56 or older with acute myeloid leukemia (AML) when treated with standard doses of Cytosine Arabinoside (Ara-C) and Daunorubicin (DNR), with or without recombinant human granulocyte-colony stimulating factor (rhG-CSF). 2) To assess the frequency and severity of toxicities of the two treatment regimens. 3) To compare the duration of neutropenia and thrombocytopenia; the total of febrile days; the number of days of antibiotic therapy; the number and type of infection episodes; and the number of hospital days in patients treated with or without recombinant human granulocyte-colony stimulating factor (rhG-CSF). 4) To correlate biological parameters including cell surface immunophenotype, ploidy and cytogenetics with clinical response.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This is a new study there is no reportable data available.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9032 Status: Ongoing

Title: A Controlled Trial of Cyclosporine As a Chemotherapy-Resistance Modifier In Blast Phase-Chronic Myelogenous Leukemia, Phase III.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: cyclosporine, Chemotherapy-Modifier
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 19 Oct 92	Results Continue

Objective(s): 1) To compare the duration of survival in patients with chronic myelogenous leukemia (CML) in blast phase, when treated with either chemotherapy (Ara-c/Daunomycin) alone, or chemotherapy plus the resistance modifier cyclosporine-A (CyA). 2) To estimate the frequency of P-glycoprotein expression and its association with blast lineage and prognosis. 3) To compare the frequency and severity of toxicity of the two treatment regimens.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9035 Status: Ongoing

Title: Randomized Trial of Adjuvant Immunotherapy with an Allogenic Melanoma Vaccine for Patients with Intermediate Thickness Node, Negative Malignant Melanoma (T3N0M0) Phase III.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Allogenic Melanoma Vaccine
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 19 Oct 92	Results Continue

Objective(s): 1) To compare disease-free survival and overall survival between patients with T3N0M0 malignant melanoma who receive adjuvant immunotherapy with an allogeneic melanoma vaccine versus no adjuvant treatment. 2) To evaluate the toxicity of adjuvant immunotherapy with an allogeneic melanoma vaccine in patients with T3N0M0 malignant melanoma.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9037 Status: Completed

Title: Prediction of Recurrence and Survival in Node Negative Breast Cancer Patients using a Panel of Prognostic Factors: A Companion Protocol to SWOG 8897.

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Breast	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 19 Oct 92 Results Continue	

Objective(s): 1) To measure the following, histologic and nuclear grade; Estrogen and progesterone receptors; HER-2 oncogene; Cathepsin D; EGF receptor; PS2; hsp27, 70 and 90, in paraffin-embedded histopathological specimens from lymph node-negative breast cancer patients. 2) To correlate the above factors with biological and clinical features including recurrence and survival in patients entered on SWOG protocol SWOG-8897, "Phase III comparison of adjuvant chemotherapy with or without endocrine therapy in high risk, node-negative breast cancer patients and a natural history follow-up study in low risk node-negative patients."

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9038 Status: Ongoing

Title: Extended Administration of Oral Etoposide and Cyclophosphamide for the Treatment of Advanced Non-Small Cell Lung Cancer Phase II Pilot.

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Lung Non-Small Cell	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	4
Date of Periodic Review	19 Oct 92 Results Continue

Objective(s): 1) To estimate the response rate of extended oral administration of etoposide and cyclophosphamide in advanced non-small cell lung cancer. 2) To evaluate the qualitative toxicities of this regimen administered in a Phase II study.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

**Detail Summary Sheet**

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**Date: 15 Dec 93 Proj No: SWOG 9039 Status: Ongoing**

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**Title: Evaluation of Quality of Life in Patients with Stage D2 Cancer of the Prostate Enrolled on SWOG-8894.**

<b>Start Date</b> FY 91	<b>Est Comp Date:</b>
<b>Principal Investigator:</b> Timothy J. O'Rourke, LTC, MC	<b>Facility:</b> Brooke Army Medical Center
<b>Dept/Svc:</b> Department of Medicine/Oncology	<b>Associate Investigators:</b> Ian M. Thompson, MAJ, MC
<b>Key Words:</b> Cancer, Prostate	
<b>Accumulative MEDCASE</b>	<b>Est Accumulative</b>
<b>Cost:</b>	<b>OMA Cost:</b>
<b>Number of Subjects Enrolled During Reporting Period:</b> 7	
<b>Total Number of Subjects Enrolled to Date:</b> 18	
<b>Date of Periodic Review</b> 19 Oct 92 <b>Results</b> Continue	

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**Objective(s):** The Cancer Control intervention study measures quality of life in patients with advanced carcinoma of the prostate. Specifically, it is a companion protocol for SWOG-8894. Treatment of Stage D2 Carcinoma of the Prostate Comparing Orchiectomy +/- Flutamide.

**Technical Approach:** Therapy will follow the schema outlined in the protocol.

**Progress:** There is no reportable data available at this time.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9040 Status: Ongoing

Title: Intergroup Rectal Adjuvant Protocol, A Phase III Study.

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, Rectal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 1	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 19 Oct 92	Results Continue

Objective(s): The objective of the proposed study is to determine the relative efficacy of: 5-FU, 5-FU and leucovorin, 5-FU and levamisole and 5-FU, leucovorin and levamisole when combined with pelvic radiation therapy in the treatment of Stages B-2 and C rectal cancer.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9045 Status: Completed

Title: Evaluation of Quality of Life in Patients with Advanced Colorectal Cancer Enrolled on SWOG-8905.

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Colorectal	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review <u>19 Oct 92</u> Results Continue	

Objective(s): This Cancer Control intervention study measures quality of life in patients with advanced colorectal cancer. Specifically, it is a companion protocol for SWOG-8905 Evaluation of Quality of Life in Patients with Advanced Colorectal Cancer Enrolled on SWOG-8905.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9054 Status: Completed

Title: Ancillary Bone Mineral Density Study in Premenopausal Women on SWOG 8851, EST 5188 (Intergroup 0101)

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Bone Mineral Density
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 19 Oct 92 Results Continue	

Objective(s): 1) To determine whether tamoxifen (10 mg BID) protects against loss of bone mineral density in the lumbar spine and in the femur in premenopausal women with breast cancer following their being made postmenopausal by cytotoxic and ovarian function-suppressing hormonal therapy. 2) To determine the effects Zoladex therapy has on bone mineral density in the lumbar spine and femur in premenopausal women with breast cancer following treatment with 6 cycles of cytotoxic chemotherapy. 3) To determine the rates, pattern of rates and pattern of bone loss in the lumbar spine and femur occurring in premenopausal women treated with a standard course of 6 cycles of cytotoxic chemotherapy. 4) The fourth objective of this study is to investigate the serum marker of bone mineral metabolism, serum osteocalcin, in a population of women undergoing significant changes in their bone density.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9058 Status: Ongoing

Title: A Phase II Trial of Intravenous Vinorelbine (Navelbine) in Previously Untreated Extensive Small Cell Lung Carcinoma.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Vinorelbine, Lung Carcinoma
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 19 Oct 92	Results Continue

Objective(s): 1) To assess whether vinorelbine (Navelbine) given as a weekly intravenous infusion produces objective clinical responses in patients with previously untreated extensive small cell lung cancer. 2) To assess the clinical and laboratory toxicities as well as patient tolerance of this dose/schedule of intravenous vinorelbine (Navelbine).

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9060 Status: Completed

Title: A Pilot Study Evaluation of Multimodality Treatment of Local regional Esophageal Carcinoma, Phase II.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Esophageal Carcinoma
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	0
Date of Periodic Review	19 Oct 92 Results Continue

Objective(s): 1) To evaluate the feasibility and toxicity of combined radiotherapy-chemotherapy with continuous infusion 5-fluorouracil plus cisplatin in epidermal carcinoma or adenocarcinoma of the middle and distal esophagus. 2) To estimate the disease-free survival and survival duration associated with this combined modality regimen.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9061 Status: Ongoing

Title: A Phase III Study of Conventional Adjuvant Chemotherapy Versus High Dose Chemotherapy and Autologous Bone Marrow Transplantation Versus Adjuvant Intensification Therapy Following Conventional Adjuvant Chemotherapy in patients with Stage II and III Breast Cancer at High Risk of Recurrence.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Breast Cancer	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 19 Oct 92	Results Continue

Objective(s): 1) To compare the sites and rates of recurrence, disease-free survival and overall survival, and toxicity of adjuvant chemotherapy (CAF) with adjuvant chemotherapy plus high-dose therapy with cyclophosphamide and ThioTEPA with autologous marrow infusion in patients with breast cancer with 10 or more positive lymph nodes. 2) To compare the efficacy and toxicity of 3 different infusion schedules of GM-CSF. 3) To prospectively evaluate the incidence and degree of occult marrow contamination due to breast cancer cells at the time of study entry and following CAF chemotherapy by analyzing samples of marrow using a panel of monoclonal antibodies specific for breast cancer. 4) To document the changes in psychosocial function that occur during treatment on the two regimens and to compare post-treatment recovery of psychosocial function.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9062 Status: Ongoing

Title: Evaluation of 96 Hour Infusion of 5-FU & Alpha Interferon in Patients with Recurrent/Metastatic Squamous Cell Carcinoma of the Head and Neck.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Metastatic Squamous cell Carcinoma
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 19 Oct 92	Results Continue

Objective(s): 1) To evaluate the complete response rate in order to assess whether this regimen should be advanced to further studies and, 2) To evaluate the qualitative and quantitative toxicities associated with this regimen and, 3) To assess the feasibility of this regimen.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available.

Detail Summary Sheet

Date: 24 Feb 94 Proj No: SWOG 9100 Status: Ongoing

Title: A Phase II Pilot Study of High-Dose 24 Hour Continuous Infusion 5-FU and Leucovorin and Low-Dose PALA for Patients with Pancreatic Adenocarcinoma

Start Date	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results Continue

Objective(s): To evaluate response rates and toxicities of 5-FU 2600 mg/m<sup>2</sup> as a 24-hour continuous intravenous infusion given once a week, in combination with Leucovorin 500 mg/m<sup>2</sup> as a 24-hour continuous infusion and PALA 250 mg/m<sup>2</sup> intravenously over 15 minutes (24 hours prior to the 5-FU) in pancreatic cancer.

Technical Approach: As outlined in the protocol schema.

Progress: This is a new study. There is no reportable data.

Detail Summary Sheet

Date: 24 Feb 94 Proj No: SWOG 9101 Status: Ongoing

Title: Evaluation of Edatrexate in Patients with Advanced or Recurrent Bladder Carcinoma, Phase II

Start Date	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: Total Number of Subjects Enrolled to Date: Date of Periodic Review	Results Continue

Objective(s): 1) Evaluate the likelihood of response in order to assess whether Edatrexate should be advanced to further studies and 2) Evaluate the qualitative and quantitative toxicities of Edatrexate.

Technical Approach: As outlined in the protocol schema.

Progress: This is a new study. There is no reportable data.

Detail Summary Sheet

Date: 24 Feb 94 Proj No: SWOG 9107 Status: Ongoing

Title: A Phase II Pilot Study of High-Dose 24-Hour Continuous Infusion 5-FU and Leucovorin and Low-Dose PALA for Patients with Colorectal Cancer.

Start Date	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative  OMA Cost:
Number of Subjects Enrolled During Reporting Period: Total Number of Subjects Enrolled to Date: Date of Periodic Review	Results Continue

Objective(s): 1) To evaluate response rates and toxicities of 5-FU 2600 mg/m<sup>2</sup> as a 24-hour continuous intravenous infusion given once a week, in combination with Leucovorin 500 mg/m<sup>2</sup> as a 24-hour continuous infusion and PALA 250 mg/m<sup>2</sup> intravenously over 15 minutes (24 hours prior to the 5-FU) in colorectal cancer.

Technical Approach: As outlined in the protocol schema.

Progress: This is a new study. There is no reportable data.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9108 Status: Ongoing

Title: A Phase III Comparison of Fludarabine Phosphate vs Chlorambucil vs Fludarabine Phosphate + Chlorambucil in Previously Untreated B-Cell Chronic Lymphocytic Leukemia.

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Leukemia, Chronic Lymphocytic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 1	
Date of Periodic Review 19 Oct 92	Results Continue

Objective(s): 1) To compare in previously untreated CLL patients the response rates and progression free survival. 2) To determine whether the quality of life is superior using any of the three regimens. 3) To determine whether Fludarabine Phosphate and chlorambucil are non-cross-resistant by a crossover design for patients failing to respond to the single agent to which they were initially randomized.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9110 Status: Ongoing

Title: A Phase II Evaluation of Didemnin B In Central Nervous System Tumors.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Central Nervous Tumors, Didemnin B
Key Words:	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period:	0
Total Number of Subjects Enrolled to Date:	0
Date of Periodic Review	19 Oct 92 Results Continue

Objective(s): 1) evaluate the likelihood of response in order to assess whether didemnin B should be advanced to further studies and, 2) evaluate the qualitative and quantitative toxicities of didemnin B.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9111 Status: Ongoing

Title: Phase III Study of Post-Operative Adjuvant Interferon Alpha 2 in Resected High-Risk Primary and Regionally Metastatic Melanoma.

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Melanoma, Metastatic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 19 Oct 92	Results Continue

Objective(s): 1) To establish the efficacy of 1 year at maximally tolerable dosages (IV and SC) interferon alfa-2b as an adjuvant to increase the disease free interval and overall survival in patients at high risk for recurrence after definitive surgery for deep primary lesions or after regional lymph node recurrence. 2) To evaluate the efficacy and tolerance of long-term Interferon alfa-2b at 3 MU/d (SC) as an adjuvant to increase the disease-free survival and overall survival patients at high risk for recurrence after definitive surgery for deep primary lesions or after regional lymph node recurrence with melanoma, in comparison to 1 year of treatment of maximally tolerable dosages.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9115 Status: Ongoing

Title: Randomized Study of Standard Chemotherapy vs STAMP V with ABMT in Stage IV poor Prognosis Breast Carcinoma, Phase III.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Breast Sarcoma,	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 19 Oct 92	Results Continue

Objective(s): 1) To compare the overall survival as well as the time to treatment failure of a high dose program with autologous stem cell infusion as consolidation treatment for patients with poor prognosis, Stage IV breast cancer at the completion of induction chemotherapy to further standard treatment (continuation of outpatient chemotherapy).

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9119 Status: Ongoing

Title: Primary Chemotherapy of Poor Prognosis Soft Tissue Sarcomas Phase II, Pilot.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Soft Tissue Sarcomas	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 19 Oct 92 Results Continue	

Objective(s): 1) To evaluate the efficacy of primary chemotherapy, wide surgical resection, adjuvant chemotherapy and radiotherapy on local control, metastasis free survival and overall survival. 2) To evaluate the utility of tumor response to primary chemotherapy as an indicator of local and systemic disease control in high grade soft tissue sarcoma. 3) To evaluate the toxicity of primary chemotherapy, surgery, adjuvant chemotherapy and radiation therapy in this patient population.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9124 Status: Ongoing

Title: Evaluation of Edatrexate in Patients with Relapsed or Refractory Germ Cell Tumors.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators: Ian M. Thompson MD
Key Words: Refractory, Germ Cell Tumors	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 19 Oct 92	Results Continue

Objective(s): 1) To assess the rate and duration of response to Edatrexate. 2) Evaluate patterns of toxicity (qualitative and quantitative) in patients treated with Edatrexate Therapy will follow the schema outlined in the protocol.

Technical Approach: This is a new study there is no reportable data available.

Progress: There is no reportable data.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9125 Status: Ongoing

Title: A Phase II Trial of CVAD/Verapamil/Quinine for the Treatment of Non-Hodgkin's Lymphoma.

Start Date FY 91	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Lymphoma, Non-Hodgkin's	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 19 Oct 92	Results Continue

Objective(s): To evaluate the effectiveness of the CVAD chemotherapy regimen (cyclophosphamide, vincristine, doxorubicin and dexamethasone) when administered in combination with chemosensitizers (verapamil and quinine) which are intended to block the emergence of multidrug resistance in previously untreated patients with intermediate and high grade non-Hodgkin's lymphomas. To assess the toxicities and side effects associated with the CVAD regimen when combined with verapamil and quinine.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available at this time.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9129 Status: Ongoing

Title: Phase III Randomized Study of All-Trans Retinoic Acid Versus Cytosine Arabinoside and Daunorubicin as Induction Therapy for Patients with Previously Untreated Acute Promyelocytic Leukemia.

Start Date FY	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Carcinoma, Non-Small Cell Lung	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: Total Number of Subjects Enrolled to Date: Date of Periodic Review	Results

Objective(s): 1) To compare the complete remission rate and disease-free survival of TRA to that achieved with conventional induction chemotherapy including Cytosine Arabinoside plus Daunorubucin in patients with previously untreated APL. 2) To compare the toxicities of TRA to those of Cytosine Arabinoside plus Daunorubicin as Induction Therapy in APL. 3) To determine the value of maintenance therapy with TRA.

Technical Approach: As outlined in the protocol schema.

Progress: This is a new study. There is no reportable data.

Detail Summary Sheet

Date: 24 Feb 94    Proj No: SWOG 9130		Status: Ongoing
Title: Smoking Cessation for Early Bladder Cancer Patients Using a Combined Brief Physician Message and Cancer Information Service (CIS) Counseling Approach		
Start Date	Est Comp Date:	
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center	
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	
Number of Subjects Enrolled During Reporting Period: _____		
Total Number of Subjects Enrolled to Date: _____		
Date of Periodic Review	Results	Continue

Objective(s): This is a two-arm randomized trial to compare the efficacy of a brief, two-staged smoking cessation intervention with "usual care" among early stage bladder cancer patients. The primary objective of this study is to assess the efficacy of a combined physician-initiated, Cancer Information Service (CIS) reinforced quit smoking intervention compared with "usual care" in terms of the one year smoking quit rate in newly diagnosed patients with early stage bladder cancer.

Technical Approach: As outlined in the protocol schema.

Progress: There have been no patients enrolled to date.

Detail Summary Sheet

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Date: 24 Feb 94 Proj No: SWOG 9133 Status: Ongoing

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Title: Randomized Trial of Subtotal Nodal Irradiation Versus Doxorubicin Plus Vinblastine and Subtotal Nodal Irradiation for Stage I-IIA Hodgkin's Disease, Phase III.

Start Date	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: Total Number of Subjects Enrolled to Date: Date of Periodic Review	Results Continue

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Objective(s): 1) The primary objective is to compare the progression-free and overall survivals of non-irradiated patients with clinical Stage I-IIA Hodgkin's Disease treated with subtotal nodal irradiation (3600-4000cGy) alone or subtotal nodal irradiation plus 3 cycles of doxorubicin and vinblastine.

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Technical Approach: As outlined in the protocol schema.

Progress: This is a new study. There is no reportable data.

Detail Summary Sheet

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Date: 15 Dec 93 Proj No: SWOG 9134 Status: Completed

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Title: A Phase II Trial of Taxol and Granulocyte-Colony Stimulating Factor (G-CSF) in Patients with Advanced Soft Tissue Sarcoma

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Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LFC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Sarcoma, Soft Tissue, Advanced	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 19 Oct 92	Results Continue

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Objective(s): 1) To evaluate the clinical response rate of taxol administered with G-CSF in advanced soft tissue sarcomas. 2) To define the qualitative and quantitative toxicities of taxol administered with G-CSF in this patient population.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9135 Status: Completed

Title: A Phase II Trial of Taxol and Granulocyte-Colony Stimulating Factor (G-CSF) in Patients with Pancreatic Adenocarcinoma.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Adenocarcinoma, Pancreatic	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 19 Oct 92 Results Continue	

Objective(s): 1) To evaluate the clinical response rate of taxol administered with G-CSF in pancreatic adenocarcinoma. 2) To define the qualitative and quantitative toxicities of taxol administered with G-CSF in this patient population.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9139 Status: Ongoing

Title: Adjuvant Therapy of Primary Osteogenic Sarcomas, Phase II.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Sarcoma, Osteogenic	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 19 Oct 92	Results Continue

Objective(s): To estimate the time to treatment failure and survival rate of the three drug combination Adriamycin, cisplatin, and ifosfamide as adjunctive treatment of osteosarcoma of the extremity. 2) To evaluate histopathologic tumor necrosis following preoperative Adriamycin, cisplatin, and ifosfamide. 3) To assess the feasibility of determining histopathologic tumor necrosis in a cooperative group setting. 4) To assess the influence of clinical prognostic variables on disease outcome. 5) To assess the toxicity of this regimen.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available.

Detail Summary Sheet

Date: 24 Feb 94 Proj No: SWOG 9140 Status: Ongoing

Title: Phase II Study of Oral Biopirimine Combined with Intravesical Bacillus Calmette-Guerin (Tice) in Patients with Carcinoma in situ of the Bladder.

Start Date	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results      Continue

Objective(s): 1) Assess the response probability in order to determine whether the combination of oral bopirimine and BCG should be advanced to further studies and 2) Evaluate the qualitative and quantitative toxicities of the combination oral bopirimine and BCG.

Technical Approach: As outlined in the protocol schema.

Progress: There have been no patients enrolled to date. There is no data to report.

Detail Summary Sheet

Date: 24 Feb 94 Proj No: SWOG 9143 Status: Ongoing

Title: A Phase II Study of Cisplatin Preceded by a 12-hour Continuous Infusion of Concurrent Hydroxyurea and Cytosine Arabinoside (Ara'C) for Patients with Untreated Malignant Mesothelioma

Start Date	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: _____	
Total Number of Subjects Enrolled to Date: _____	
Date of Periodic Review	Results      Continue

Objective(s): 1) To evaluate the response rate of patients with mesothelioma following treatment with this three-drug program. 2) To evaluate the qualitative and quantitative toxicity spectrum of this regimen.

Technical Approach: As outlined in the protocol schema.

Progress: This is a new study. There is no reportable data.

Detail Summary Sheet

Date: 24 Feb 94 Proj No: SWOG 9148 Status: Ongoing

Title: A Phase II Study of Cisplatin Preced by a 12 Hour Continuous Infusion of Concurrent Hydroxyurea and Cytosine Arabinoside (ARA-C) for Patients with Untreated, Extensive Stage Small Cell and Non-Small Cell Lung Carcinoma

Start Date	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period:	
Total Number of Subjects Enrolled to Date:	
Date of Periodic Review	Results      Continue

Objective(s): 1) To evaluate the response rate of this program in patients with extensive-stage small cell lung cancer (ENSCLC). 2) To evaluate the response rate of this program in patients with extensive-stage small cell lung cancer (ESCLC). 3) To assess the qualitative and quantitative toxicities of this regimen in each patient population.

Technical Approach: As outlined in the protocol schema.

Progress: This is a new study. There is no reportable data.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9150 Status: Ongoing

Title: Evaluation of Topotecan in Gastric Cancer, Phase II

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Cancer, Gastric	
Accumulative MEDCASE	Est Accumulative
Cost:	OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 19 Oct 92 Results Continue	

Objective(s): 1) To evaluate the response rate of gastric carcinoma treated with topotecan. 2) To evaluate the qualitative and quantitative toxicities of topotecan administered in a Phase II study.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9151 Status: Ongoing

Title: Evaluation of Topotecan in Hepatoma, Phase II.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words: Hepatoma	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review <u>19 Oct 92</u> Results Continue	

Objective(s):

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: This study is closed to new patient accrual, open for followup purposes only.

Detail Summary Sheet

Date: 15 Dec 93 Proj No: SWOG 9152 Status: Ongoing

Title: Prediction of Recurrence and Therapy Response in Advanced Germ Cell Tumors by DNA Flow Cytometry.

Start Date FY 92	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: 0	
Total Number of Subjects Enrolled to Date: 0	
Date of Periodic Review 19 Oct 92	Results Continue

Objective(s): 1) To determine the proliferative activity and presence of aneuploidy within paraffin-embedded histopathologic specimens from patients with advanced disseminated (poor prognosis) GCT. 2) To correlate proliferative activity and aneuploidy with clinical features including response to therapy, relapse-free survival, and overall survival in patients entered on ECOG protocol EST 3887/SWOG 8997/CALGB 8991; Phase III Chemotherapy of Disseminated Advanced Stage Testicular Cancer with Cisplatin plus Etoposide with either Bleomycin or Ifosfamide.

Technical Approach: Therapy will follow the schema outlined in the protocol.

Progress: There is no reportable data available.

Detail Summary Sheet

Date: 24 Feb 94 Proj No: SWOG 9158 Status: Ongoing

Title: Evaluation of Trans Retinoic Acid and Alpha Interferon in Patients with Squamous Cell Carcinoma of the Lung (STAGE IV)

Start Date	Est Comp Date:
Principal Investigator: Timothy J. O'Rourke, LTC, MC	Facility: Brooke Army Medical Center
Dept/Svc: Department of Medicine/Oncology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
Number of Subjects Enrolled During Reporting Period: Total Number of Subjects Enrolled to Date: Date of Periodic Review	Results Continue

Objective(s): 1) To assess the response rate to trans-Retinoic Acid and Alpha Interferon used in a daily schedule for patients with advanced, well differentiated squamous cell carcinoma of the lung. 2) To further define the qualitative toxicities of this regimen administered to this patient population in a Phase II study.

Technical Approach: As outlined in the protocol schema.

Progress: This is a new study. There is no reportable data.

**Detail Summary Sheet**

**Date:** 24 Feb 94

**Protocol Number:** SWOG 9201

**Status:** Ongoing

**Title:** "Phase III Trial to Preserve the Larynx: Induction Chemotherapy and Radiation Therapy versus Concomitant Chemotherapy and Radiation Therapy versus Radiation."

<b>Start date:</b>	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Timothy J. O'Rourke, COL, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Hematology/Oncology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_

**Total number of subjects enrolled to date:** \_\_\_\_\_

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** The primary endpoint is survival with preservation of laryngeal function. In achieving this overall goal the following outcomes will be assessed: 1) Length of disease-free survival with a preserved larynx. 2) Length of overall survival. 3) Evaluation of tumor response at the completion of chemotherapy prior to RT for induction chemotherapy (Arm 1) and at the completion of RT for concomitant treatment (Arm 2). 4) Patterns of relapse: local and regional recurrence and distant metastasis. The incidence of second primary tumors. 5) Incidence of adverse effects: acute and late. 6) Concomitant morbidity of neck dissection and/or laryngeal salvage surgery. 7) QOL for patients with laryngeal preservation versus patients requiring salvage laryngectomies. 8) To evaluate QOL outcomes between patients receiving radiation therapy alone and those receiving adjuvant therapy.

**Technical Approach:** As outlined in the protocol schema.

**Progress:** This is a new study. There is no reportable data.

**Detail Summary Sheet**

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**Date: 15 Dec 93      Protocol Number: SWOG 9205      Status: Ongoing**

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**Title: Central Prostate Cancer Serum Repository Protocol**

<b>Start date:</b>	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Timothy J. O'Rourke, COL, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Hematology/Oncology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_

**Total number of subjects enrolled to date:** \_\_\_\_\_

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) To store serum of patients with cancer of the prostate entered onto clinical trials conducted by the Southwest Oncology Group Genitourinary Committee. 2) To provide the serum of the above patients entered on Southwest Oncology Group studies for specific clinical-laboratory investigations (e.g. evaluation of a new marker) outlined on separate Southwest Oncology Group protocols approved by the Genitourinary Committee Tumor Biology Subcommittee.

**Technical Approach:** As outlined in the protocol schema.

**Progress:** There have been no patients enrolled this year.

**Detail Summary Sheet**

**Date:** 24 Feb 94

**Protocol Number:** SWOG 9210

**Status:** Ongoing

**Title:** "A Phase III Randomized Trial of Combination Therapy for Multiple Myeloma Comparison of (1) VAD-P to VAD-P/Quinine for Induction: (2) Randomization of Prednisone Dose Intensity for Remission Maintenance"

<b>Start date:</b>	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Timothy J. O'Rourke, COL, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Hematology/Oncology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_  
**Total number of subjects enrolled to date:** \_\_\_\_\_  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) To compare the effectiveness of the VAD-P chemotherapy regimen when administered alone or in combination with the chemosensitizer quinine intended to block the emergence of multidrug resistance during remission induction in previously untreated patients with multiple myeloma. This will be evaluated in terms of response ( $\geq$  50% regression), overall and relapse-free survival, and P-glycoprotein expression prior to therapy at the end of induction therapy in relation to the induction therapy arm. 2) To evaluate the chemosensitizing potential of quinine to reverse drug resistance in myeloma patients randomized to VAD-P induction who fail to achieve at least 25% regression with chemotherapy alone. 3) To compare the value of alternate day prednisone (10 mg) versus 50 mg of prednisone for remission maintenance for patients proven to achieve at least 25% regression. The effectiveness of the two maintenance arms will be compared in terms of the duration of relapse-free survival and overall survival from the time of randomization of maintenance therapy.

**Technical Approach:** As outlined in the protocol schema.

**Progress:** This is a new study. There is no reportable data.

Detail Summary Sheet

Date: 24 Feb 94      Protocol Number: SWOG 9215      Status: Terminated

Title: Quality of Life on Breast Cancer Adjuvant Trial EST 3189.

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To compare quality of life (BCQ scores), during treatment in patients receiving CAF or a 16 week regimen in EST 3189 (SWOG 8931) (this will constitute the primary comparison of the study).

Technical Approach: As outlined in the protocol schema.

Progress: This is a new study. There is no reportable data.

**Detail Summary Sheet**

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Date: 24 Feb 94    Protocol Number: SWOG 9216    Status: Ongoing

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Title: "A Randomized Phase III Study of CODE Plus Thoracic Irradiation Versus Alternating CAV and EP for Extensive Stage Small Cell Lung Cancer, (NCIC CTG)."

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine whether the CODE regimen plus thoracic irradiation is superior to standard alternating CAV and EP in the treatment of extensive stage small cell lung cancer in terms of: 1) overall survival; 2) time to disease progression; 3) response rate; 4) response duration; 5) quality of life.

Technical Approach: As outlined in the protocol schema.

Progress: This is a new study. There is no reportable data.

**Detail Summary Sheet**

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**Date: 15 Dec 93      Protocol Number: SWOG 9217      Status: Ongoing**

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**Title: "Chemoprevention of Prostate Cancer with Finasteride (Proscar), Phase III Intergroup."**

<b>Start date:</b>	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Timothy J. O'Rourke, COL, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Hematology/Oncology	<b>Associate Investigator(s):</b> LTC Ian M. Thompson, MC
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_  
**Total number of subjects enrolled to date:** \_\_\_\_\_  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To test the difference in the biopsy-proven prevalence of carcinoma of the prostate between a group of participants treated with finasteride and a group treated with placebo for seven years.

**Technical Approach:** As outlined in the protocol schema

**Progress:** This is a new study. There is no reportable data.

**Detail Summary Sheet**

**Date: 24 Feb 94      Protocol Number: SWOG 9218      Status: Ongoing**

**Title: "Measurement of O<sup>6</sup> MGMT in Patients with High Grade Primary Brain Tumors Treated with Radiation Therapy and BCNU, Ancillary Study"**

<b>Start date:</b>	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Timothy J. O'Rourke, COL, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Hematology/Oncology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_

**Total number of subjects enrolled to date:** \_\_\_\_\_

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To explore the prognostic significance of O<sup>6</sup>-Methylguanine-DNA Methyltransferase (O<sup>6</sup> MGMT) in predicting survival among patients with high grade gliomas receiving BCNU and radiation therapy, and to develop a preliminary definition of good risk/poor risk categories based on low/high levels of O<sup>6</sup> MGMT tissue levels.

**Technical Approach:** As outlined in the protocol schema.

**Progress:** This is a new study. There is no reportable data.

**Detail Summary Sheet**

**Date:** 24 Feb 94      **Protocol Number:** SWOG 9240      **Status:** Terminated

**Title:** A Phase II Trial of CVAD for Treatment of Non-Hodgkin's Lymphoma

<b>Start date:</b>	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Timothy J. O'Rourke, COL, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Hematology/Oncology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_

**Total number of subjects enrolled to date:** \_\_\_\_\_

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) To evaluate the effectiveness of the CVAD chemotherapy regimen (cyclophosphamide, vincristine, doxorubicin and dexamethasone) in previously untreated patients with intermediate and high grade non-Hodgkin's lymphoma. The effectiveness of CVAD will be based on the estimate of the complete response rate and the time to treatment failure.

**Technical Approach:** As outlined in the protocol schema.

**Progress:** This is a new study. There is no reportable data.

Detail Summary Sheet

Date: 24 Feb 94      Protocol Number: SWOG 9248      Status: Ongoing

Title: A Phase II Trial of Paclitaxel (TAXOL) in Patients with Metastatic Refractory Carcinoma of the Breast

Start date:	Estimated completion date:
Principal Investigator: Timothy J. O'Rourke, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Medicine/Hematology/Oncology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To evaluate the subjective improvement in patients with symptomatic refractory carcinoma of the female breast treated with paclitaxel. 2) To evaluate the clinical response rate of paclitaxel in patients with refractory carcinoma of the female breast. 3) To evaluate the qualitative and quantitative toxicities of paclitaxel in a Phase II study.

Technical Approach: As outlined in the protocol schema.

Progress: This is a new study. There is no reportable data.

**Detail Summary Sheet**

**Date:** 23 Feb 94      **Protocol Number:** SWOG 9303      **Status:** Ongoing

**Title:** "Phase III Study of Radiation Therapy, Levamisole and 5-Fluorouracil versus 5-Fluorouracil and Levamisole in Selected Patients with Completely Resected Colon Cancer"

<b>Start date:</b>	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Timothy J. O'Rourke, COL, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Medicine/Hematology/Oncology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_

**Total number of subjects enrolled to date:** \_\_\_\_\_

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) The primary goal of this study will be to determine whether 5FU, levamisole and radiation therapy results in superior overall survival when compared to 5FU and levamisole without radiation therapy in the management of patients with completely resection pathologic stage T<sub>4</sub>N<sub>0</sub>-2 colon cancer and selected patients with T<sub>3</sub>N<sub>1</sub>-2 colon cancer. 2) Disease-free survival, patterns of failure and toxicity will also be evaluated. If radiation therapy improves disease-free survival, patterns of failure and toxicity will also be evaluated. If radiation therapy improves disease-free survival or freedom from local failure without improving survival consideration may be given to further evaluation of RT in subsequent trials. The additional of radiation therapy will only be declared to have definitive patient benefit, however, if it results in superior survival.

**Technical Approach:** As outlined in the protocol schema.

**Progress:** This is a new study. There is no reportable data.

**Detail Summary Sheet**

**Date:** 31 Dec 93      **Protocol Number:** POG 7799      **Status:** Ongoing

**Title:** Rare Tumor Registry for Childhood Solid Tumor Malignancies.

<b>Start date:</b> 25 Sep 81	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Terry E. Pick, COL, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Pediatrics	<b>Associate Investigator(s):</b> Allen R. Potter, LTC, MC
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 0

**Total number of subjects enrolled to date:** 1

**Periodic review date:** 9 Jul 90      **Review results:** Continue

**Objective(s):** 1) To collect natural history data on malignancies which occur so rarely that large series of patients cannot be accumulated any single institution.

2) To evaluate therapies in those groups of rare tumors in which fair numbers of cases can be accrued.

**Technical Approach:** Any child under the age of 18 years at diagnosis with a rare solid tumor is eligible for the study.

**Progress:** Open study. No new patients this year. Recommend study remain open for patient accrual.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 8104      Status: Completed

Title: Comprehensive Care of the Child with Neuroblastoma: A Stage and Age Oriented Study, Phase III.

Start date: 27 Jan 83	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Allen R. Potter, LTC, MC
Key Words: Neuroblastoma	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 8

Periodic review date: 9 Jul 90      Review results: Continue

Objective(s): 1) To treat the tumor according to age and stage at which the tumor was diagnosed.

2) To reduce later complications by separating by age and stage those patients that require surgery only; surgery and chemotherapy; surgery, chemotherapy, and radiation therapy.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study closed to new patient accrual. Three patients remain on followup with no problems.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 8340      Status: Completed

Title: Allogenic or Autologous Bone Marrow Transplantation (BMT) for Stage D Neuroblastoma: A POG Pilot Study.

Start date: 12 Aug 85	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center
Department/Service: Department of Pediatrics	Associate Investigator(s): Walter H. Harvey, MAJ, MC John J. Posch Barbara Reeb
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4

Total number of subjects enrolled to date: 22

Periodic review date: 9 Jul 90      Review results: Closed to new entries

Objective(s): 1) To determine the response rate and duration of patients aged > 1 year with metastatic (Stage D) neuroblastoma to intensive chemotherapy and fractionated total body irradiation followed by allogeneic or autologous bone marrow transplantation (BMT) performed in first clinical remission.  
2) To determine the response rate and duration using the same regimen in patients with Stage D neuroblastoma who fail to respond to, or recur after, conventional chemotherapy.  
3) To determine the toxicity of the above regimen.

Technical Approach: This pilot study tests the efficacy and toxicity of high dose melphalan and fractionated total body irradiation supported by allogeneic or autologous BMT for neuroblastoma in first clinical remission or following relapse.

Bone marrow aspiration and therapy will follow the schema outlined in the study protocol.

Progress: Study remains open for followup of patients only.

**Detail Summary Sheet**

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Date: 31 Dec 93      Protocol Number: POG 8600/01/02      Status: Completed

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Title: Evaluation of Treatment Regimens in Acute Lymphoid Leukemia in Childhood (AlinC #14) - A Pediatric Oncology Group Phase III Study.

Start date: 28 Mar 86	Est Comp Date: Closed 1990
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words: Leukemia, Lymphoid	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4

Total number of subjects enrolled to date: 10

Periodic review date: 9 Apr 93      Review results: Open only for followup

Objective(s): 1) To test the concept that intensive asparaginase (ASP) therapy designed to maintain low asparagine levels for the first six months of maintenance will improve the outcome of patients with standard risk acute lymphocytic leukemia (ALL) when added to pulses of intermediate dose methotrexate (MTX) as compared to intensification with IDM alone.  
2) To study the effectiveness in standard risk patients of intensification with a potentially synergistic or additive drug pair, i.e. IDM plus AraC, as compared to that of intensification with IDM pulses alone.  
3) To determine if administering a pulse of IDM + AraC at 3 week intervals during the first 4 months of complete remission in children with ALL is superior to administering the same number of IDM + AraC pulse at 23-week intervals during the first 2 years of complete remission in children with ALL with either "lower" or "higher" risk of relapse.  
4) To obtain further information on the immediate and delayed toxicity of the continuation of chemotherapy program that incorporates these combinations of MTX and AraC or MTX and ASP in moderately high doses.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study closed, continue followup of patients.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 8625/26      Status: Completed

Title: Combined Therapy and Restaging in the Treatment of Stages I, IIA, and IIIA, Hodgkin's Disease in Pediatric Patients.

Start date: 30 Jul 86	Est Comp date: 01 Sep 92
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words: Hodgkin's	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 3

Periodic review date: 9 Jul 90      Review results: Continue

Objective(s): 1) To compare the effectiveness of 3 cycles of MOPP/ABVD vs 2 cycles of MOPP/ABVD plus low dose radiation therapy in terms of duration of remission and eventual survival (with one cycle = 1 course MOPP and 1 course of ABVD) in children with early stage Hodgkin's disease.

2) To compare the incidence and severity of acute/long-term toxicity of MOPP/ABVD vs MOPP/ABVD plus involved field, low dose radiation therapy.

3) To evaluate the incidence of CR after 2 cycles of MOPP/ABVD.

4) To search for prognostic factors that may correlate with duration of survival.

5) To determine the salvage rate of patients who fail to respond to 2 cycles of MOPP/ABVD or who fail to achieve a CR after completion of prescribed therapy.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study closed except for followup.

Detail Summary Sheet

Date: 31 Dec 93

Protocol Number: POG 8650

Status: Ongoing

Title: National Wilms Tumor Study - 4: Stage I/Favorable or Anaplastic Histology.

Start date: 19 Dec 86	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words: Wilms tumor	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: 3

Periodic review date: 9 Jul 90 Review results: Continue

Objective(s): To gain a better understanding of the Wilms's tumor by gathering detailed information regarding gross and histologic morphology and to correlate this information with treatment and clinical outcome.

Technical Approach: Patients will be randomized according to stage and histology.

Therapy will follow the schema outlined in the study protocol.

Progress: Study remains open. Two patients were entered on study this year. A total of five have been entered and are being followed.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 8651      Status: Ongoing

Title: Osteosarcoma #2: A Randomized Trial of Pre-Surgical Chemotherapy vs Immediate Surgery and Adjuvant Chemotherapy in the Treatment of Non-Metastatic Osteosarcoma.

5

Start date: 27 Mar 87	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: 9 Jul 90      Review results: Continue

Objective(s): To determine whether chemotherapy administered prior to and after the definitive surgery of the primary tumor can improve the disease-free and/or overall survival of patients with non-metastatic osteosarcoma of the extremity or resectable bone when compared to the traditional approach of surgical treatment of the primary tumor followed by adjuvant chemotherapy.

Technical Approach: To be eligible for this study, the patient must be under 30 years of age, have no prior history of cancer and no prior therapy other than biopsy.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients entered to date.

**Detail Summary Sheet**

**Date:** 31 Dec 93      **Protocol Number:** POG 8654      **Status:** Ongoing

**Title:** A Study of Soft Tissue Sarcomas Other Than Rhabdomyosarcoma and Its Variants.

<b>Start date:</b>	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Terry E. Pick, COL, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Pediatrics	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: 9 Jul 90      Review results: Continue

**Objective(s):** 1) To determine whether adjuvant chemotherapy with vincristine, adriamycin, cyclophosphamide, and actinomycin D (VACA) increases the relapse-free survival (RFS) of patients with localized soft tissue sarcoma (STS) who are in complete response (CR) status after surgery with or without postoperative radiation.

2) To compare VACA with VACA plus DTIC (VACAD) therapy in regard to CR and RFS rates in patients with: (a) metastatic STS at diagnosis or (b) previously "untreated" recurrent STS (patients on the no chemotherapy control arm of "adjuvant" study 8653) or (c) localized persistent gross residual STS after surgery and radiation therapy.

**Technical Approach:** Therapy will follow the schema outlined in the study protocol.

**Progress:** POG 8654 remains open. No new patients entered.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 8691      Status: Ongoing

Title: T-Cell #3 Pilot Study.

Start date: 30 Jul 86	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1

Total number of subjects enrolled to date: 3

Periodic review date: 9 Jul 90      Review results: Continue

Objective(s): 1) To determine the toxicity and complications associated with the administration of this intensive chemotherapy regimen to children with T-cell leukemia and advanced state T-cell lymphoma.

2) To determine the feasibility of using this chemotherapy regimen as the backbone of a randomized groupwide T-cell study evaluating intensive L-asparaginase therapy.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study remains open for patient accrual.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 8704      Status: Completed

Title: T-Cell #3 Protocol - A POG Phase III Study.

Start date: 3 Sep 87	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0  
Total number of subjects enrolled to date: 0  
Periodic review date: 9 Jul 90      Review results: \_\_\_\_\_

Objective(s): 1) To estimate the disease-free survival of a multiagent chemotherapy regimen designed to be particularly effective for patients with T-cell derived lymphoid malignancies in children with advanced stage lymphoblastic lymphoma and T-cell acute lymphoblastic leukemia.

2) To determine the efficacy of adding intensive high-dose L-asparaginase to the backbone chemotherapy regimen in an attempt to improve disease-free survival.

Technical Approach: Patients <21 years and >12 months with a diagnosis of ALL, or patients age <21 years with a diagnosis of lymphoblastic lymphoma will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Study closed. However, two patients are currently being followed.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 8725      Status: Completed

Title: Randomized Study of Intensive Chemotherapy (MOPP/ABVD) +/- Low Dose Total Nodal Radiation Therapy in the Treatment of Stages IIB, IIIA, IIIB, and IV Hodgkin's Disease in Pediatric Patients.

Start date: 29 Jul 88	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 2

Periodic review date: 9 Jul 90      Review results:

Objective(s): To determine, in a randomized study, whether the addition of low dose total nodal radiation therapy (TNRT) in pediatric patients with Hodgkin's disease who have achieved a complete remission after receiving 4 courses of MOPP alternating with 4 courses of ABVD will improve the duration of complete remission and survival when compared to patients who have received chemotherapy alone.

To determine whether TNRT will significantly increase either acute toxicity or long-term morbidity when compared to MOPP/ABVD alone.

To determine the effect of chemotherapy as compared to chemotherapy plus TNRT on splenic function as determined by the pitted erythrocyte count using Nomarski optics.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study now closed. Two patients in followup.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 8741/42      Status: Ongoing

Title: Stage D NBL #3: Treatment of Stage D Neuroblastoma in Children >365 Days at Diagnosis.

Start date: 3 Sep 87	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2

Total number of subjects enrolled to date: 2

Periodic review date: 9 Jul 90      Review results: Continue

Objective(s): To evaluate response rates and toxicity of four sequentially administered Phase II chemotherapy agents when given prior to conventional therapy in patients >365 days of age with Stage D (metastatic) neuroblastoma. The specific agents to be studied are: ifosfamide, carboplatin (CBDCA), cis-dichloro-transdihydroxy-bis-platinum (CHIP), and epirubicin.

Technical Approach: Any patient with newly diagnosed metastatic (Stage D) neuroblastoma who is >365 days and <21 years of age, who has received no previous chemotherapy or irradiation therapy, and who has measurable disease will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Study now closed for patient accrual. Two patients for followup.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 8743      Status: Ongoing

Title: Treatment in 'Better Risk' Neuroblastoma: POG Stage B (All Ages) and POG Stage C, D, and DS (VS) <365 Days.

Start date: 3 Sep 87	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Allan R. Potter, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1

Total number of subjects enrolled to date: 1

Periodic review date: 9 Jul 90      Review results: Continue

Objective(s): 1) To prospectively identify patients <365 days of age at diagnosis who will fail to achieve CR with cyclophosphamide (CYC) and Adriamycin (ADR) and delayed surgery; then to alter therapy in these patients and evaluate the CR and survival rates with alternate therapy, using cis-platinum (CDDP) and VM-26.

2) To evaluate the disease-free survival (DFS) and survival in a larger group of patients currently considered to be "better risk" patients with neuroblastoma.

Technical Approach: Patient eligibility and therapy will follow the schema outlined in the study protocol.

Progress: One patient remains on followup with no evidence of disease. Although the study has been closed to new entries, it remains open for follow-up.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 8820      Status: Completed

Title: VP-16, AMSA+/l 5 Azacytidine in Refractory ANLL, Phase II/III.

Start date: 13 Mar 89	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	

Number of subjects enrolled during reporting period: 1  
Total number of subjects enrolled to date: 2  
Periodic review date: 9 Jul 90      Review results: Continue

Objective(s): 1) to compare, in a randomized study, the remission rate of VP-16/AMSA versus VP-16/AMSA/5-AZA in children with recurrent or refractory acute non-lymphocytic leukemia (ANLL).

2) To determine the duration of remission, using pulses of the induction regimen as continuation therapy.

3) To study the relative toxicities of these two therapies.

Technical Approach: Patients < 21 years of age at the time initial diagnosis who have either failed to respond to induction therapy or who are in first relapse are eligible for this study. Therapy will follow the schema outlined in the study protocol.

Progress: Study closed. One patient alive and being followed.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 8821      Status: Completed

Title: AML#3 Intensive Multiagent Therapy vs Autologous Bone Marrow Transplant Early in 1st CR for Children with Acute Myelocytic Leukemia.

Start date: 29 Jul 88	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 2

Total number of subjects enrolled to date: 9

Periodic review date: 9 Jul 90      Review results: Continue

Objective(s): To determine the disease-free survival (DFS) and event-free survival (EFS) in childhood acute myelocytic leukemia (AML) offered by intensive chemotherapy with alternating non-cross resistant drug combinations for nine courses.

To determine if short (three course) intensive chemotherapy (identical to the first three courses of the above regimen) followed by autologous bone marrow transplant (BMT) using the Busulfan/Cytoxan preparative regimen and 4-hydroxycyclophosphamide (4-HC) purged marrow is effective therapy.

To compare, in a randomized study, the results of the above 2 regimens and to correlate the treatment outcome with clinical and laboratory features.

Technical Approach: Patient eligibility and therapy will follow the schema outlined in the study protocol.

Progress: Study closed. Nine patients entered; four patients alive and being followed.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 8823      Status: Ongoing

Title: Recombinant Alpha-Interferon in Childhood Myelogenous Leukemia, Phase II.

Start date: 10 Jul 89	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date:      Review results:

Objective(s): To determine toxicity, response rate and duration of response to therapy with recombinant alpha interferon for newly diagnosed myelogenous leukemia (ACML) in chronic phase, and for "juvenile" chronic myelogenous leukemia (JCML) occurring within the first two decades.

Technical Approach: Eligible patients must have been < 21 years of age at the time of initial diagnosis and must not have received prior anti-neoplastic therapy. Therapy will follow the schema outlined in the study protocol.

Progress: Study remains open. No patients entered this year.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 8828      Status: Ongoing

Title: Late Effects of Treatment of Hodgkin's Disease, Non-therapeutic Study.

Start date: 12 Jun 89	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: 9 Jul 90      Review results: Continue

Objective(s): To estimate the incidence of various late effects seen in patients with Hodgkin's disease treated by the regimens of POG 8625 and 8725. In particular to focus on known sequelae of Hodgkin's disease and its treatment.

Technical Approach: All patients registered on front-line phase III POG Hodgkin's disease therapeutic studies POG 8625 and POG 8725 after the opening of this study will be eligible and must be registered on this study unless the patient or parent/guardian refuses.

Progress: Study remains open. No patients entered.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 8829      Status: Ongoing

Title: A Case Control Study of Hodgkin's Disease in Childhood - A Nontherapeutic Study.

Start date: 10 Jul 89	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: 9 Jul 90      Review results: Continue

Objective(s): To conduct first interview case-control study of childhood Hodgkin's disease to learn more about the epidemiology of the disease in children.

Technical Approach: All pediatric oncology patients, less than 15 years of age with a newly confirmed diagnosis of Hodgkin's disease are eligible. Telephone interview and administration of questionnaire will be conducted.

Progress: Study remains open. No patients entered.

**Detail Summary Sheet**

**Date:** 31 Dec 93      **Protocol Number:** POG 8844      **Status:** Completed

**Title:** Stage D Neuroblastoma #4: Bone Marrow Transplant in the Treatment of Children > 365 Days at Diagnosis with Stage D Neuroblastoma.

<b>Start date:</b> 12 Dec 88	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Terry E. Pick, COL, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Pediatrics	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 0

**Total number of subjects enrolled to date:** 3

**Periodic review date:** 9 Jul 90      **Review results:** Continue

**Objective(s):** 1) To determine whether the outcome of children > 365 days with Stage D neuroblastoma who are treated at institutions offering an autologous bone marrow transplant (ABET) option to conventional therapy and who have good initial response to conventional therapy, is better than the outcome of similar children who are treated at institutions which do not offer the transplant option.

2) To evaluate the toxicities associated with this protocol.

**Technical Approach:** Patients >365 days and <21 years at diagnosis previously registered on POG 8741/42 who have completed post-induction evaluation and post induction surgery are eligible. Therapy will follow the schema outlined in the study protocol.

**Progress:** Study now closed. Three patients entered. Study remains open for followup.

**Detail Summary Sheet**

**Date:** 31 Dec 93      **Protocol Number:** POG 8850      **Status:** Ongoing

**Title:** Evaluation of Vincristine, Adriamycin, Cyclophosphamide, and Dactinomycin With or Without the Addition of Ifosfamide and Etoposide in the Treatment of Patients With Newly Diagnosed Ewing's Sarcoma or Primitive Neuroectodermal Tumor of Bone, Phase III.

<b>Start date:</b> 13 Mar 89	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Terry E. Pick, COL, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Pediatrics	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 0  
**Total number of subjects enrolled to date:** 1  
**Periodic review date:** 9 Jul 90      **Review results:** Continue

**Objective(s):** To determine the event-free survival and survival of patients with Ewing's sarcoma and PNET of the bone who are treated with etoposide and ifosfamide in combination with standard therapy, and to compare their EFS and survival rates with those of patients treated with standard therapy alone.

**Technical Approach:** Patients <30 years of age with newly diagnosed Ewing's sarcoma and PNET of bone, or a diagnosis compatible with primitive sarcoma of bone are eligible. Therapy will follow the schema outlined in the study protocol.

**Progress:** Study closed. One patient in followup.

**Detail Summary Sheet**

**Date:** 31 Dec 93      **Protocol Number:** POG 8862      **Status:** Ongoing

**Title:** Treatment of First Marrow Relapse and/or Extramedullary Relapse of Childhood Acute T-Lymphoblastic Leukemia and T-Non-Hodgkin's Lymphoma with Combination Chemotherapy Including 2'-Deoxycoformycin, Phase II.

<b>Start date:</b> 12 Jun 89	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Terry E. Pick, COL, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Pediatrics	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 0

**Total number of subjects enrolled to date:** 0

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) To assess the toxicity and efficacy of low dose deoxycoformycin (DCF) given as IV bolus injection in prolonging the duration of remission for patients with T-ALL/T-NHL in second remission.

2) To determine the correlation of clinical response and toxicities with plasma levels of adenosine deaminase (ADA), adenosine (ado) and deoxyadenosine (dado), dATP/ATP ratios in RBCs, and in vitro sensitivity of leukemia cells to DCF plus dado.

3) To determine the efficacy of IV methotrexate and IV 6-mercaptopurine in patients with T-ALL, and T-NHL.

**Technical Approach:** Patients < 21 years of age at time of diagnosis in first relapsed documented by aspirate or biopsy are eligible. Therapy will follow the schema outlined in the study protocol.

**Progress:** No patients have been entered to date.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 8930      Status: Ongoing

Title: A Comprehensive Genetic Analysis of Brain Tumors.

Start date: 10 Jul 89	Estimated completion date:
Principal Investigator: Terry A. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: 9 Jul 90      Review results: Continue

Objective(s): To determine prospectively the clinical significance of abnormalities of cellular DNA content, as measured by flow cytometry and to determine the clinical implications of cytogenetic abnormalities in pediatric brain tumors.

Technical Approach: Any patient with a brain tumor who has had tumor tissue submitted for study and who is subsequently registered on a POG frontline therapeutic protocol is eligible for this study.

Progress: Study remains open for patient entry.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 8935      Status: Ongoing

Title: A Study of the Biological Behavior of Optic Pathway Tumors, Phase II.

Start date: 10 Jul 89	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: 9 Jul 90      Review results: Continue

Objective(s): 1) To assess time to progression of optic pathway tumors (OPTs).

2) To estimate the response rate of radiation therapy in children with OPTs, when measured at 2 years post-irradiation.

Technical Approach: Patients < 21 years of age at the time of diagnosis with imaging evidence of intraorbital or chiasmatic mass with or without visual loss are eligible. Within two weeks following surgery, slides will be submitted to pathology for review.

Progress: No patients entered. Study remains open for patient entry.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 8936      Status: Ongoing

Title: Phase II Study of Carboplatin (CBDCA) in the Treatment of Children with Progressive Optic Pathway Tumors.

Start date: 10 Jul 89	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: 9 Jul 90      Review results: Continue

Objective(s): To assess the response rate to CBDCA in children < 5 years of age with optic pathway tumors and to assess the efficacy of CBDCA in delaying progression of disease.

Technical Approach: Patients will be eligible for treatment on this study if they meet the eligibility criteria for POG 8935, if they are < 5 years of age and if there is evidence of progressive disease. Therapy will follow the schema outlined in the study protocol.

Progress: Study open. No new patients entered on study.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 9000      Status: Ongoing

Title: ALinC 15 Laboratory Classification Protocol for Acute Lymphoblastic Leukemia.

Start date: 17 Dec 90	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Allan R. Potter, LTC, MC
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 5  
Total number of subjects enrolled to date: 10  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the specific subtype of leukemia in order to plan treatment.

Technical Approach: All eligible patients will undergo bone marrow aspiration followed by specific blood studies as outlined in the study protocol.

Progress: Study remains open. Five patients entered this year. Total patients entered-10.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 9005      Status: Ongoing

Title: ALinC 15: Dose Intensification of Methotrexate and 6-Mercaptopurine for ALL in Childhood.

Start date: 18 Dec 90	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4

Total number of subjects enrolled to date: 7

Periodic review date:      Review results:

Objective(s): To determine, in a randomized trial, whether intensification with intermediate-dose methotrexate (ID MTX), and intravenous 6-mercaptopurine (IV 6-MP) is superior or inferior to repeated low-dose, oral methotrexate (LDMTX) and IV 6-MP for prevention of relapse in children with ALL in first remission and at lower risk for relapse.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study open. Four new patients entered. Total patients entered: 7.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 9006      Status: Ongoing

Title: ALinC 15: Up-Front 6-MP/MTX vs Up-Front Alternating chemotherapy for Acute Lymphocytic Leukemia in Childhood.

Start date: 18 Dec 90	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s): Terry E. Pick, COL, MC
Key Words:	

Number of subjects enrolled during reporting period: 2  
Total number of subjects enrolled to date: 3  
Periodic review date: Review results:

Objective(s): To compare, in a randomized trial of children with ALL at higher risk for relapse, the efficacy and toxicity of A: 12 early intensive courses of IV methotrexate (TMX) plus IV 6-mercaptopurine (6-MP) vs B: 12 early intensive courses of alternating intensive chemotherapy combinations (6-MP/MTX), VM-26/Ara-C, vincristine/prednisone/PEG-L-asparaginase/daunomycin/Ara-C.

Technical Approach: Randomization and therapy will follow the schema outlined in the study protocol.

Progress: Two patients entered on study this year. Study remains open.

**Detail Summary Sheet**

**Date:** 31 Dec 93      **Protocol Number:** POG 9031      **Status:** Ongoing

**Title:** Treatment of Children with High-Stage Medulloblastoma: Cisplatin/VP-16 Pre- vs Post-Irradiation.

<b>Start date:</b> 24 Aug 90	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Terry E. Pick, COL, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Pediatrics	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 1

**Total number of subjects enrolled to date:** 1

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) To compare the 2-year event-free survival (EFS) of children with newly-diagnosed high-risk medulloblastoma who are treated with cisplatin and VP-16 pre-irradiation vs post-irradiation.

2) To define the toxicity and activity of pre- and post-irradiation cisplatin/VP-16 in patients with newly-diagnosed high-risk medulloblastoma.

3) To determine whether achievement of a measurable tumor response (PR and CR) to pre-irradiation cisplatin/VP-16 has prognostic significance for children with high-risk medulloblastoma, compared with failure to achieve a measurable (SD or PD).

**Technical Approach:** Patients age > 3 years and < 21 years registered within 4 weeks of initial diagnostic surgery or biopsy are eligible.

**Therapy** will follow the schema outlined in the study protocol.

**Progress:** Study remains open. One patient remains in followup.

**Detail Summary Sheet**

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**Date:** 31 Dec 93      **Protocol Number:** POG 9046      **Status:** Ongoing

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**Title:** Molecular Genetic Study of Wilms' Tumor and Nephrogenic Rests.

<b>Start date:</b> 31 May 90	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Terry E. Pick, COL, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Pediatrics	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 2

**Total number of subjects enrolled to date:** 2

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) To define the patterns of tumor-specific loss of constitutional chromosomal heterozygosity in a large series of Wilms' tumors and associated nephrogenic rests (nephroblastomatosis).  
2) To correlate these patterns with clinicopathologic findings, to be able, thereby, to propose a new model of pathogenesis for Wilms' tumor.  
3) To physically localize gene mutations and chromosome abnormalities from specific categories of Wilms' tumors on a long-range physical map of the short arm of chromosome 11.  
4) To clone genes associated with Wilms' tumor.  
5) To establish a bank of molecularly and cytogenetically characterized Wilms tumors with matched constitutional tissue.

**Technical Approach:** Any patient < 16 years of age, with a previously untreated histologically proven Wilms' tumor of any histologic subtype or a mesoblastic nephroma, who has had tumor tissue and blood submitted for study, is eligible. Patients diagnosed prior to the opening of this study are also eligible if both unfixed, frozen pre-treatment tumor and a source of constitutional DNA are available.

**Study procedures are outlined in the protocol.**

**Progress:** Study remains open. Two patients entered on study.

**Detail Summary Sheet**

**Date:** 31 Dec 93      **Protocol Number:** POG 9047      **Status:** Ongoing

**Title:** Neuroblastoma Biology Protocol.

<b>Start date:</b> 31 May 90	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Terry E. Pick, COL, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Pediatrics	<b>Associate Investigator(s):</b> Allen R. Potter, LTC, MC
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 2

**Total number of subjects enrolled to date:** 3

**Periodic review date:**      **Review results:**

**Objective(s):**

- 1) To analyze the DNA content of neuroblastoma cells by flow cytometry.
- 2) To characterize neuroblastoma tumor DNA from POG patients genetically by analysis of N-myc amplification and LOH chromosome 1p.
- 3) To determine the independent clinical significance of these and other genetic rearrangements compared to more conventional clinical, histologic, and biological variables in predicting either response to treatment or outcome.
- 4) To develop a reference bank of genetically characterized tumor tissue and DNA that would be available for other current, planned, and future studies of neuroblastoma biology.

**Technical Approach:** Tumor tissue submitted from diagnostic biopsies or marrow aspirations will be cryopreserved for biologic studies. Eligibility requirements of active neuroblastoma therapeutic studies will require that all patients be concomitantly registered on this study.

Flow cytometry and N-myc studies will be done as outlined in the study protocol.

**Progress:** Study remains open. Two patients entered on study.

**Detail Summary Sheet**

**Date:** 31 Dec 93

**Protocol Number:** POG 9048

**Status:** Ongoing

**Title:** Treatment of Children with Localized Malignant Germ Cell Tumors: A Phase II Study.

<b>Start date:</b>	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Terry E. Pick, COL, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Pediatrics	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 0

**Total number of subjects enrolled to date:** 0

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) To determine whether > 85% of patients with immature teratomas or Stage I malignant testicular germ cell tumors will have long-term event-free survival when treated with surgery alone, and to estimate a time after which disease recurrence for these patients is very unlikely. 2) To determine whether a long-term event-free survival of > 85% can be achieved for children with stage II malignant testicular germ cell tumors and Stage I or II ovarian germ cell tumors who are treated with four courses of chemotherapy with cisplatin, etoposide, and bleomycin. 3) To evaluate the prognostic significance of histology, site, and size of the primary lesion(s); extension of disease into local tissues; and extent of lymph node involvement. 4) To determine whether initial levels and subsequent changes in tumor markers, specifically alpha-fetoprotein, beta-human chorionic gonadotropin, and LDH, correlate with initial response, ultimate outcome, and disease recurrence.

**Technical Approach:** Eligible patients must have primary germ cell tumors of the testes or ovaries, which are histologically verified to be yolk-sac tumor, embryonal carcinoma, choriocarcinoma, immature teratoma, or teratoma with malignant elements. Therapy will follow the schema outlined in the study protocol.

**Progress:** Study remains open. No patients enrolled to date.

**Detail Summary Sheet**

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**Date:** 31 Dec 93      **Protocol Number:** POG 9049      **Status:** Ongoing

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**Title:** Study of High-Risk Malignant Germ Cell Tumors in Children.

<b>Start date:</b> 31 May 90	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Terry E. Pick, COL, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Pediatrics	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 0

**Total number of subjects enrolled to date:** 0

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) To compare the efficacy with respect to survival and event-free survival of two chemotherapeutic regimens high-dose cisplatin, etoposide, and bleomycin or standard-dose cisplatin, etoposide, and bleomycin in the treatment of children with high-risk malignant germ cell tumors.

2) To evaluate the prognostic significance of histology, site, and size of the primary lesion(s), sites of metastasis, and extent of lymph node involvement.

3) To determine whether initial levels and subsequent changes in tumor markers correlate with initial response, ultimate outcome, and the risk of disease progression.

**Technical Approach:** Patients age < 21 years with histologically verified yolk-sac tumor, embryonal carcinoma, choriocarcinoma, chygerminoma (seminoma), or teratoma with mixed malignant elements are eligible. Chemotherapy must begin within 2 working days of randomization and within 21 days of the most recent diagnostic surgical procedure.

Therapy will follow the schema outlined in the study protocol.

**Progress:** Study remains open. No patients have been entered on this study.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 9060      Status: Ongoing

Title: Intensive QOD Ifosfamide for the Treatment of Recurrent or Progressive CNS Tumors.

Start date: 31 Aug 90	Estimated completion date:
Principal Investigator: Terry A. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine the activity of ifosfamide delivered every other day x 3 in the treatment of children with recurrent or progressive brain tumors.

2) To quantitate the toxicity associated with treatment as above.

Technical Approach: Patients < 21 years are eligible if they have had prior histological confirmation of primary intracranial or spinal cord tumor with MR or CT documentation of progressive or recurrent disease after therapy of higher priority.

Therapy will follow the schema outlined in the study protocol.

Progress: Study remains open. No patients have been entered into this study.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 9061      Status: Ongoing

Title: The Treatment of Isolated Central Nervous System Leukemia.

Start date: 31 Aug 90	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: Review results:

Objective(s): 1) To determine the efficacy and toxicity of intensified systemic treatment with delayed craniospinal irradiation for children with acute lymphoblastic leukemia and isolated central nervous system disease.

2) To describe the pharmacokinetics and cytotoxic effect within the cerebrospinal fluid (CSF) of intravenous 6-mercaptopurine (6-MP) given as a single agent in an "up-front" window and to determine the level at which 100% of the blasts are cleared from the CSF.

3) To measure parameters of CNS tissue injury and associate these with the effects of CNS leukemia and treatments.

Technical Approach: Patients with a diagnosis of ALL in first bone marrow remission with isolated, initial CNS relapse are eligible. Patients must be > 1 year of age at time of CNS relapse and must not have had prior brain irradiation.

Therapy will follow the schema outlined in the study protocol.

Progress: Study remains open. No patients have been entered into this study.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 9072      Status: Ongoing

Title: Ifosfamide, Carboplatin, Etoposide (ICE) Treatment of Recurrent/Resistant Malignant Solid Tumors of Childhood.

Start date: 31 Aug 90	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1

Total number of subjects enrolled to date: 1

Periodic review date:      Review results:

Objective(s): 1) To determine the antitumor activity and toxicity of ifosfamide (IFOS), etoposide (VP-16) plus escalating doses of carboplatin (CBDCA) against childhood malignant solid tumors resistant to conventional chemotherapy.  
2) To establish a dose level of carboplatin, when given in the presence of IFOS and VP-16, that results in maximum tolerable toxicity, which is predictable and reversible.  
3) To determine the maximum time of maximum toxicity and time to recovery after ICE therapy.  
4) To determine if there is cumulative toxicity in the child after administration of ICE.

Technical Approach: All patients must be < 21 years of age with documented measurable disease, confirmed with appropriate histologic examination, are eligible. Patients must have progressive or recurrent disease that is resistant to conventional therapy and must not have been entered on any prior phase I trials.

Therapy will follow the schema outlined in the study protocol.

Progress: Study remains open. No new patients entered on study. One patient died.

**Detail Summary Sheet**

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**Date:** 31 Dec 93      **Protocol Number:** POG 9107      **Status:** Ongoing

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**Title:** Infant Leukemia Protocol.

<b>Start date:</b> 18 Mar 91	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Terry E. Pick, COL, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Pediatrics	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 0

**Total number of subjects enrolled to date:** 0

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) To determine the toxicity associated with one year of intensive post-induction chemotherapy consisting of rotating courses of high-dose Ara-C/DNR, IV 6-MP/MTX, VP-16/Ara-C, vincristine/prednisone/Cytoxan/Ara-C given to patients < 12 months of age with acute lymphatic leukemia in remission.

2) To determine the incidence, severity, and duration of neutropenia, thrombocytopenia, and anemia associated with each of the above courses.

3) To determine other systemic toxicities (infections, nutritional, etc.) associated with this intensive one-year post-induction chemotherapy.

4) To determine the feasibility of using this regimen in a groupwide phase III protocol for patients < 12 months of age with acute lymphatic leukemia.

**Technical Approach:** Therapy will follow the schema outlined in the study protocol.

**Progress:** Study remains open. No patients enrolled to date.

**Detail Summary Sheet**

**Date:** 31 Dec 93      **Protocol Number:** POG 9110      **Status:** Ongoing

**Title:** SIMAL #6: Rotational Drug Therapy After 1st Marrow Relapse on Non-T, Non-B Acute Lymphoblastic Leukemia (ALL).

Start date: 20 May 91	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1

Total number of subjects enrolled to date: 1

Periodic review date: Review results:

**Objective(s):** 1) To determine the feasibility and toxicity of administering continuous infusion doxorubicin when given as a single agent in an "Investigational Window" to patients with ALL in first marrow relapse.

2) To assess the feasibility and toxicity of a rotating weekly parenteral drug regimen for continuing remission of non-T, non-B ALL in children after first histologic relapse.

3) A secondary goal is estimating the leukemic cell kill in patients receiving continuous infusion doxorubicin in an "Investigational Window".

**Technical Approach:** Therapy will follow the schema outlined in the study protocol.

**Progress:** Study closed. One patient remains on followup.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 9132      Status: Ongoing

Title: Hyperfractionated Irradiation for Posterior Fossa Ependymoma, A Phase II/III Study

Start date: 16 Mar 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine the feasibility of using hyperfractionated irradiation to the posterior fossa and upper cervical canal to treat newly-diagnosed patients with posterior fossa ependymoma, and to determine the toxicity of this treatment. 2) To evaluate the response of children with incompletely-resected posterior fossa ependymoma to hyperfractionated irradiation. 3) To estimate the disease control interval and pattern of failure of children with posterior fossa ependymoma following treatment with surgery and hyperfractionated irradiation.

Technical Approach: All eligible patients will receive therapy as outlined in the study protocol.

Progress: Study remains open for patient enrollment.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 9136      Status: Ongoing

Title: Phase I/II Dose Escalating Trail of Hyperfractionated Irradiation in the Treatment of Supratentorial Malignant Tumors of Childhood.

Start date: 19 Aug 91	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine the feasibility of using limited volume hyperfractionated radiation therapy to treat children with localized supratentorial malignant gliomas (Group A).  
2) To determine the feasibility of using hyperfractionated craniospinal irradiation to treat children with poorly-differentiated supratentorial embryonal tumors (PFTEs) or supratentorial malignant gliomas associated with neuraxis dissemination (Group B).

Additional objectives as outlined in the study protocol.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study remains open. 0 patients entered into study.

**Detail Summary Sheet**

**Date:** 31 Dec 93      **Protocol Number:** POG 9139      **Status:** Completed

**Title:** A Dose-Escalating Study of Cisplatin Used Concomitantly with Hyperfractionated Irradiation in the Treatment of Children with Newly Diagnosed Brain Stem Gliomas.

<b>Start date:</b> 20 May 91	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Allen R. Potter, LTC, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Pediatrics	<b>Associate Investigator(s):</b> Terry E. Pick, COL, MC
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 1

**Total number of subjects enrolled to date:** 1

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) To determine the acute and subacute toxicities associated with the administration of cisplatin by continuous infusion, to be used as a radio-sensitizer given simultaneously with a previously tested hyperfractionated irradiation regimen in children with newly-diagnosed brain stem glioma (BSG).

2) To establish the dose level of infusional cisplatin that results in maximum tolerated toxicity when combined with hyperfractionated radiotherapy to the brain stem.

**Technical Approach:** Therapy will follow the schema outlined in the study protocol.

**Progress:** Study closed. One patient died. No patients on followup.

**Detail Summary Sheet**

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**Date:** 31 Dec 93      **Protocol Number:** POG 9140      **Status:** Ongoing

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**Title:** Therapy for Recurrent or Refractory Neuroblastoma.

<b>Start date:</b> 25 Feb 91	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Terry E. Pick, COL, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Pediatrics	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 0

**Total number of subjects enrolled to date:** 0

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) To determine the response rate and toxicity of three different regimens used to treat patients with resistant or recurrent neuroblastoma: a) Treatment 1 - High-dose cisplatin (HDP) with sodium thiosulfate (STS) plus high-dose VP-16 (HDVP); b) Treatment 2 - high-dose cisplatin (HD-CBDCA) with VP-16 (VP); and c) Treatment 3 - ifosfamide (IFOS) and MESNA with carboplatin (CBDCA).

2) To evaluate the efficacy of 13-cis retinoic acid (RA) in prolonging time to progression of disease for patients with resistant or recurrent neuroblastoma who achieve a response following induction chemotherapy.

3) To measure plasma levels of RA attained during therapy and to determine the correlation of these levels with response to treatment and clinical toxicity.

4) To measure retinoic acid nuclear receptors (RARs) in tumor tissue and to determine their significance in predicting response to therapy.

**Technical Approach:** Therapy will follow the schema outlined in the study protocol.

**Progress:** Study remains open. No new patients.

**Detail Summary Sheet**

**Date:** 31 Dec 93      **Protocol Number:** POG 9170      **Status:** Ongoing

**Title:** Ifosfamide, Etoposide and G-CSF in Treatment of Recurrent/Resistant Malignant Sarcomas of Childhood, including Osteosarcoma, Rhabdomyosarcoma, .

<b>Start date:</b> 25 Feb 91	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Terry E. Pick, COL, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Pediatrics	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 0

**Total number of subjects enrolled to date:** 0

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) To establish the qualitative and quantitative toxicity of Etoposide (VP-16), ifosfamide (IFOS), and G-CSF administered to children whose cancer is refractory to standard therapy. 2) To establish a dose level of Ifosfamide with VP-16 and G-CSF that results in maximum-tolerable toxicity, which is predictable and reversible (MTD). 3) To establish the acute and chronic dose-limiting toxicities (DLT) of the combinations of VP-16, IFOS, and G-CSF with increasing doses of IFOS in children. 4) To determine if there is cumulative toxicity in children after administration of 3 cycles of therapy.

**Technical Approach:** Therapy will follow the schema outlined in the study protocol.

**Progress:** Study ongoing. No new patients.

Detail Summary Sheet

Date: 31 Dec 93

Protocol Number: POG 9079

Status: Completed

Title: Pilot Study, High-Dose Melphalan and Cyclophosphamide with ABM Rescue for Recurrent/Progressive Malignant Brain Tumors

Start date: 16 Mar 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine the acute and delayed toxicities of melphalan and cyclophosphamide followed by ABM rescue in patients with recurrent/progressive brain tumors. 2) To establish the dose level of cyclophosphamide that results in maximum tolerated non-hematologic toxicity, when combined with melphalan. 3) To determine duration of maximum toxicity and time to recovery. 4) To estimate response to therapy, and time to tumor progression.

Technical Approach: Bone marrow harvesting will be carried out as outlined in the study protocol.

Progress: Study closed. Two additional patients entered for a total of three.

**Detail Summary Sheet**

**Date:** 31 Dec 93      **Protocol Number:** POG 9082      **Status:** Ongoing

**Title:** Protocol for the Development of Intervention Strategies to Reduce the Time Between Symptom Onset and Diagnosis of Childhood Cancer

<b>Start date:</b> 16 Dec 91	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Terry E. Pick, COL, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Pediatrics	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_

**Total number of subjects enrolled to date:** \_\_\_\_\_

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) To describe the constellation of signs and symptoms which occur prior to the definitive diagnosis of childhood cancer. 2) To evaluate factors which may be associated with the length of time between the onset of symptoms and diagnosis. 3) To determine if the pattern of symptoms and the length of time between symptom onset and diagnosis influence prognosis independent of treatment and the stage of disease at diagnosis. 4) To provide information which may be used to develop intervention strategies aimed at reducing the interval between onset of symptoms and diagnosis.

**Technical Approach:** Eligible patients will receive therapy as outlined in the study protocol.

**Progress:** Study remains open to patient enrollment. No patients entered to date.

**Detail Summary Sheet**

**Date:** 31 Dec 93

**Protocol Number:** POG 9130

**Status:** Ongoing

**Title:** Treatment of Newly-Diagnosed Low Grade Astrocytomas, A Phase III Study

<b>Start date:</b> 27 Jan 92	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Terry E. Pick, COL, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Pediatrics	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_

**Total number of subjects enrolled to date:** \_\_\_\_\_

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) To determine the beneficial effects of irradiation in newly diagnosed low-grade astrocytomas of the brain in childhood. 2) To define the role of surgical resection in newly diagnosed low-grade astrocytomas of the brain in childhood. 3) To determine if adjuvant radiation therapy improves progression-free survival following incomplete surgical resection in children 5-21 years old with newly diagnosed low-grade astrocytomas of the brain. To document the natural history of newly diagnosed low-grade astrocytomas of the brain in patients receiving radical surgical resection as the sole treatment modality. 5) To determine and compare the late effects and neuropsychological sequelae of the various treatments in a large group of children with slow growing brain tumors likely to have long-term progression-free survival or cure.

**Technical Approach:** All eligible patient will receive treatment as outlined in the study protocol.

**Progress:** Study remains open for patient enrollment. One patient entered and on followup.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 9193      Status: Ongoing

Title: Autologous Bone Marrow Transplantation for Recurrent/Refractory Non-Hodgkin's Lymphoma

Start date: 16 Mar 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine the therapeutic feasibility and acute toxicity of treatment in patients with recurrent non-Hodgkin's lymphoma receiving high-dose chemotherapy or chemoradiotherapy and rescued with autologous bone marrow transplantation (ABMT). 2) To estimate the survival of patients with recurrent HBL using chemotherapy or chemoradiotherapy followed by ABMT.

Technical Approach: All eligible patients will receive treatment as outlined in the study protocol.

Progress: Study remains open for patient accrual. One patient entered on study.

Detail Summary Sheet

Date: 31 Dec 93

Protocol Number: POG 9190

Status: Ongoing

Title: Intensive Chemotherapy for Stage III Diffuse Undifferentiated Non-Hodgkin's Lymphoma (Burkitt's and Non-Burkitt's

Start date: 22 Apr 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To evaluate the toxicity of high-dose Ara-C infusion following high-dose methotrexate, in combination with vincristine and fractionated cyclophosphamide. 2) To correlate Ara-C levels in serum and CSF with toxicity observed.

Technical Approach: All eligible patients will be treated as outlined in the study protocol.

Progress: Study remains open for patient enrollment.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 9222      Status: Ongoing

Title: Mitoxantrone, Etoposide and Cyclosporine (MEC) Therapy in Pediatric Patients with Acute Myeloid Leukemia

Start date: 22 Apr 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine the remission rate and toxicity to mitoxantrone, etoposide and cyclosporine. 2) To measure mdrl and topoisomerase II messenger RNA levels by PCR in myeloid leukemia cells prior to starting therapy. 3) To detect mdrl p-glycoprotein and function in leukemic blasts.

Technical Approach: All eligible patients will be treated as outlined in the study protocol.

Progress: Study remains open for patient enrollment. One patient entered on study died.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 9225      Status: Ongoing

Title: 1) To evaluate the activity of a new combined modality therapy in advanced-stage Hodgkin's disease (APE/OPPA with integrated "ping pong" low-dose radiotherapy). 2) To decrease late toxicity while maintaining therapeutic efficacy in the treatment of advanced-stage Hodgkin's disease.

Start date: 16 Mar 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To evaluate the activity of a new combined modality therapy in advanced-stage Hodgkin's disease (APE/OPPA with integrated "ping pong" low-dose-radiotherapy. 2) To decrease late toxicity while maintaining therapeutic efficacy in the treatment of advanced-stage Hodgkin's disease.

Technical Approach: Patients less than 21 years of age with histologic proof of Hodgkin's disease will receive therapy as outlined in the study protocol.

Progress: Study remains open for patient enrollment.

Detail Summary Sheet

Date: 31 Dec 93

Protocol Number: POG 9243

Status: Ongoing

Title: Treatment for Children with Intermediate-Risk Neuroblastoma: POG Stage B (All Ages) and Stages C, D, and DS (<365 Days at Diagnosis)

Start date: 22 Apr 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine and compare the acute and long-term toxicities experienced by patients treated on Arm A with patients who previously received the same treatment without G-CSF on POG #8743. 2) To determine the acute and long-term toxicities associated with treatment on Arm B. 3) To assess the relationship of specific biological features of neuroblastoma, as determined on POG #9047, to clinical presentation, response to therapy, and survival. 4) To use G-CSF to ameliorate myelosuppression and its associated morbidity, and thus potentially to reduce the cost of therapy. 5) To determine if G-CSF can improve the dose interval, and therefore the dose intensity on Arm A, compared to that achieved on POG #8743. 6) To determine the short and long-term toxicities associated with the use of G-CSF in infants.

Technical Approach: All eligible patients will be enrolled for therapy as outlined in the study protocol.

Progress: Study remains open for patient enrollment. One patient has been entered on study.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 9259      Status: Ongoing

Title: Carboplatin in the Treatment of Newly-Diagnosed Metastatic Osteosarcoma or Unresected Osteosarcoma

Start date: 16 Mar 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To estimate the response rate to carboplatin in patients presenting with newly-diagnosed metastatic or unresectable osteosarcoma prior to treatment with other chemotherapeutic agents.

Technical Approach: All eligible patients with metastatic disease or unresectable osteosarcoma will receive therapy as outlined in the study protocol.

Progress: Study remains open for patient enrollment.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: POG 9264      Status: Ongoing

Title: Chemotherapy Regimen for Initial Induction Failures in Childhood Acute Lymphoblastic Leukemia - A Pediatric Oncology Group Phase II Study

Start date: 16 Mar 92	Estimated completion date:
Principal Investigator: Terry E. Pick, COL, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Pediatrics	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To estimate the complete remission rate for initial induction failures in childhood ALL based on an induction regimen of methotrexate and 6-mercaptopurine. 2) To estimate the one-year disease-free survival for initial induction failures in childhood ALL, based on a new regimen. 3) To try and better characterize this unique subpopulation of patients with primary drug resistance using cDNA probes for the multidrug-resistant phenotype and obtain an oncogene profile.

Technical Approach: All patients less than 21 years of age at time of initial diagnosis with acute lymphoblastic (T or B cell lineage) leukemia will receive therapy as outlined in the study protocol.

Progress: Study remains open for patient enrollment.

**Detail Summary Sheet**

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**Date:** 31 Dec 93      **Protocol Number:** POG 9280      **Status:** Ongoing

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**Title:** Neuroblastoma Epidemiology Protocol

<b>Start date:</b> 16 Mar 92	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Terry E. Pick, COL, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Pediatrics	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

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**Number of subjects enrolled during reporting period:** \_\_\_\_\_

**Total number of subjects enrolled to date:** \_\_\_\_\_

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

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**Objective(s):** To evaluate the relationship between environmental exposures and the occurrence of neuroblastoma. 2) To evaluate the relative importance of risk factors for neuroblastoma reported in previous epidemiologic studies. 3) To collect information on additional potential risk factors that can be used to develop new hypotheses such as parental smoking, parental radiation exposure, family history of cancer, gestational and delivery history. 4) To determine the relationship between environmental factors and host factors by evaluating subgroups of cases defined by biologic factors and clinical characteristics.

**Technical Approach:** Study will include majority of cases newly diagnosed in the US and Canada each year who are registered by the two clinical trials groups. Controls will be identified by using random digit dialing procedure. Case and control parents will be interviewed by telephone. Clinical and biologic data will be collected as part of the cooperative group biological and therapeutic protols will be used to define subgroups of patients.

**Progress:** Study remains open for data accrual.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: GOG 26      Status: Ongoing

Title: Master Protocol for Phase II Drug Studies in Treatment of Advanced, Recurrent Pelvic Malignancies.

Start date: Reopened Feb 91	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1 (26 LL)

Total number of subjects enrolled to date: 1

Periodic review date:      Review results:

Objective(s): This protocol constitutes a Phase II design outlining the procedures that will be performed to screen for activity of new agents or drug combinations in patients with advanced recurrent pelvic malignancies. Its intent is to determine the efficacy of chemotherapeutic agents in patients whose advanced malignancies have been resistant to high priority methods of treatment.

Technical Approach: This is a study of multiple chemotherapeutic agents. Therapy will follow the schema outlined in the study protocol.

Progress: This study remains open.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: GOG 26-A      Status: Ongoing

Title: Master Protocol for Phase II Drug Studies in Treatment of Advanced, Recurrent Pelvic Malignancies

Start date: 16 Mar 92	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: Review results:

Objective(s): To evaluate a succession of new agents (cytotoxic drugs, hormones, biologic response modifiers) in a fair and efficient manner, identify active agents and provide the group with this information so that more effective regimens for the treatment of ovarian cancer can be developed.

Technical Approach: The intent of this protocol is to search for activity of new agents or drug combinations in patients with advanced or recurrent pelvic malignancies. Study design will be primarily based on prior GOG experience in the specific disease entities. This will insure consistency in evaluation of response. Therapy plans demonstrating activity will later be compared and investigated in ensuing Phase III studies.

Progress: Study remains open for data accrual

Detail Summary Sheet

Date: 31 Dec 93

Protocol Number: GOG 26-LL

Status: Ongoing

Title: A Phase II Trial of Prolonged Oral Etoposide (VP-16) in Patients with Advanced Pelvic Malignancies

Start date: 22 Apr 92	Estimated completion date:
Principal Investigator: LTC Allan R. Mayer, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: Review results:

Objective(s): To evaluate a succession of new agents (cytotoxic drugs, hormones, biologic response modifiers) in a fair and efficient manner, identify active agents and provide the group with this information so that more effective regimens for the treatment of ovarian cancer can be developed.

Technical Approach: The intent of this protocol is to search for activity of new agents or drug combinations in patients with advanced or recurrent pelvic malignancies. Study design will be primarily based on prior GOG experience in the specific disease entities. This will insure consistency in evaluation of response. Therapy plans demonstrating activity will later be compared and investigated in ensuing Phase III studies.

Progress: Study remains open for data accrual.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: GOG 41      Status: Completed

Title: Surgical Staging of Ovarian Carcinoma.

Start date: FY 79	Estimated completion date:
Principal Investigator: David R. Doering, MAJ, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: 1

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine the spread of ovarian carcinoma in intraperitoneal structures and retroperitoneal lymph nodes by direct examination, cytologic sampling, and biopsy.

2) To establish a surgical protocol for patients entered into GOG ovarian cancer treatment protocols.

3) To determine the complication rate of the procedures.

Technical Approach: Patients with all histologic types of primary ovarian cancer are eligible, including epithelial tumors, germ cell tumors, stromal tumors, and all others. Patients must be entered within two weeks of the last surgery.

Therapy will follow the schema outlined in the study protocol.

Progress: Study closed March 1993.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: GOG 45      Status: Completed

Title: Evaluation of Vinblastine, Bleomycin and Cis-Platinum in Stage III and IV Recurrent Malignant Germ Cell Tumors of the Ovary, Phase II.

Start date: 25 Jul 90	Estimated completion date:
Principal Investigator: Allan R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetric/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: 1  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Status: Study closed March 1993.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: GOG 52      Status: Completed

Title: A Phase III Randomized Study of Cyclophosphamide plus Adriamycin plus Platinol (Cis-Platinum) vs Cyclophosphamide/Platinol in Patients with Optimal Stage III Ovarian Adenocarcinoma.

Start date: 25 Jul 90	Estimated completion date:
Principal Investigator: Allan R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: 1  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Status: Study closed March 1993.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: GOG 73      Status: Completed

Title: A Clinicopathologic Study of Primary Malignant Melanoma of the Vulva Treated by Modified Radical Hemivulvectomy.

Start date: 25 Jul 90	Estimated completion date:
Principal Investigator: Allan R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 1

Periodic review date: Review results:

Objective(s): 1) To determine the relationship of histopathologic parameters (including microstaging of primary malignant melanoma of the vulva) to FIGO staging and ultimate prognosis.

Technical Approach: All patients receiving primary therapy for primary malignant melanoma of the vulva are eligible. Patients must have at least a modified radical hemivulvectomy and must be entered no later than 8 weeks of initiation of primary therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: Study closed 1993.

**Detail Summary Sheet**

**Date:** 31 Dec 93      **Protocol Number:** GOG 81F      **Status:** Ongoing

**Title:** A Phase II Trial of Tamoxifen Citrate in Patients with Advanced or Recurrent Carcinoma Responsive to Progestins

<b>Start date:</b> 16 Dec 91	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> MAJ Kevin Hall, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Obstetrics and Gynecology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 0

**Total number of subjects enrolled to date:** 0

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) To determine whether patients with endometrial carcinoma who have responded to medroxyprogesterone acetate and then progressed will respond to a second hormonal manipulation in the form of tamoxifen citrate. 2) To evaluate the level of efficacy (response rate) of tamoxifen in patients with advanced or recurrent endometrial carcinoma not previously exposed to hormonal therapy for their malignancy.

**Technical Approach:** Patients will receive tamoxifen 20 mg p.o. BID and treatment will be continued until there is evidence of disease progression. Patients will be seen at least once monthly for 3 months after initiation of therapy. If disease process is at least stable, subsequent visits may be less frequent but must occur at least every 3 months.

**Progress:** Study remains open for data accrual.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: GOG 85      Status: Completed

Title: A Randomized comparison of Hydroxyurea vs. 5-FU Infusion and Bolus Cisplatin as an Adjunct to Radiation Therapy in Patients with Stages IIB, III, and IV-A Carcinoma of the Cervix and Negative Para-Aortic Nodes.

Start date: 25 Jul 90	Estimated completion date:
Principal Investigator: Allan R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine whether hydroxyurea or the combination of 5-FU and cisplatin is superior as a potentiator of radiation therapy in advanced cervical carcinoma.

2) To determine the relative toxicities of hydroxyurea vs. the combination of 5-FU and cisplatin when given concurrently with radiation therapy.

Technical Approach: Patients with primary, previously untreated, histologically confirmed invasive squamous cell carcinoma, adenocarcinoma or adenosquamous carcinoma of the uterine cervix, Stages II-B, III-A, and IV-A, with negative para-aortic nodes are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Study closed March 1993.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: GOG 87      Status: Ongoing

Title: Master Protocol for Phase II Drug Studies in the Treatment of Recurrent or Advanced Uterine Sarcomas.

Start date: 20 May 91	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date:      Review results:

Objective(s): To identify new agents and agent combinations for the treatment of patients with recurrent or advanced metastatic sarcoma.

Technical Approach: Therapy for each phase II drug study will follow the schedule outlined in the study protocol. In addition to the master protocol, the study has been approved for 87F - Doxorubicin and Ifosfamide with Mesna.

Progress: No patients have been entered on this study.

**Detail Summary Sheet**

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**Date:** 31 Dec 93      **Protocol Number:** GOG 93      **Status:** Ongoing

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**Title:** Evaluation of Intraperitoneal Chromic Phosphate Suspension Therapy Following Negative Second Look Laparotomy for Epithelial Ovarian Carcinoma (Stage III).

<b>Start date:</b> 25 Jul 90	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> MAJ Kevin Hall, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Obstetrics and Gynecology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_

**Total number of subjects enrolled to date:** \_\_\_\_\_

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To evaluate the role of intraperitoneal chromic phosphate suspension (intraperitoneal <sup>32</sup>P) therapy in patients with Stage III epithelial ovarian carcinoma who have no detectable evidence of disease at the second-look laparotomy.

**Technical Approach:** Patients with primary histologically confirmed epithelial carcinoma of the ovary in clinical remission are eligible. Patients with no persistent or recurrent cancer as assessed by surgical, cytologic and histologic findings at the second-look laparotomy likewise are eligible.

**Therapy will follow the schema outlined in the study protocol.**

**Progress:** No patients have been entered on this study.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: GOG 94      Status: Completed

Title: A Phase II Study of Whole Abdominal Radiation in Stage I and II Papillary Serous Carcinoma.

Start date: 24 Aug 90	Estimated completion date:
Principal Investigator: Allan R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine the survival and progression free interval of patients with maximally debulked advanced endometrial carcinoma treated with abdominal radiation therapy.

2) To determine the progression free interval and site of recurrence in patients with Stage I and II papillary serous carcinoma of the endometrium treated with abdominal radiation therapy with pelvic boost.

Technical Approach: Patients meeting the inclusion criteria will undergo therapy as outlined in the study protocol.

Progress: Study closed March 1993.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: GOG 95      Status: Ongoing

Title: Randomized Clinical Trial for the Treatment of Women with Selected IC and II(A,B,C) and Selected Stage IAI & IAIIC and BII Ovarian Cancer (Phase III).

Start date: 24 Aug 90	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To compare the progression free interval and overall survival of the two treatment regimens.

2) To determine the patterns of relapse for each form of therapy.

3) To define the relative toxicities of the two treatment approaches.

Technical Approach: Patients meeting the eligibility criteria will be treated in accordance with the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: GOG 99      Status: Ongoing

Title: A Phase III Randomized Study of Surgery vs. Surgery Plus Adjunctive Radiation Therapy in Intermediate Risk Endometrial Adenocarcinoma.

Start date: 24 Aug 90	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 4

Total number of subjects enrolled to date: 4

Periodic review date: Review results:

Objective(s): 1) To determine if patients with intermediate risk endometrial adenocarcinoma (as defined below), who have no spread of disease to their lymph nodes, benefit from postoperative pelvic radiotherapy.

2) To evaluate how the addition of pelvic radiotherapy will alter the site and rate of cancer recurrence in these intermediate risk patients.

Technical Approach: Patients with primary histologically confirmed Grades 1, 2, and 3 endometrial adenocarcinoma are eligible. Patients must have had a total abdominal hysterectomy, bilateral salpingo-oophorectomy, selective and para-aortic node sampling, pelvic washings and are found to be surgical Stage I and occult Stage II. Myometrial invasion must be present.

Therapy will follow the schema outlined in the study protocol.

Progress: Study remains open for patient enrollment. Four patients have entered study thus far.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: GOG 102      Status: Ongoing

Title: Master Protocol for Phase II Intraperitoneal Drug Studies in Treatment of Minimal Residual Ovarian Malignancies Documented at Second-Look Surgery.

Start date: 15 Apr 91	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine the activity of various drugs or BRMs alone or in combination when used by the intraperitoneal route in patients who have persistent minimal residual disease epithelial ovarian malignancies after standard therapy.

2) To evaluate further the toxicity, systemic and local, of drugs and BRMs or combinations used in this study.

Technical Approach: Therapy for the following arms will follow the schema outlined in the study protocol: 102F - Alpha Recombinant Interferon (aIFN); 102G - Cisplatin and Thiotepa; and 102H - Interleukin-2; and 102N - Intraperitoneal Recombinant Alpha-2-Interferon.

Progress: No patients have been entered on this study.

**Detail Summary Sheet**

**Date:** 31 Dec 93      **Protocol Number:** GOG 104      **Status:** Completed

**Title:** Intraperitoneal Cis-Platinum/Intravenous Cyclophosphamide vs Intravenous Cis-Platinum/Cyclophosphamide in Patients with Non-Measurable (Optimal Stage III) Ovarian Cancer, Phase III Intergroup.

<b>Start date:</b> 24 Aug 90	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Allan R. Mayer, LTC, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Obstetrics and Gynecology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 0

**Total number of subjects enrolled to date:** 0

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) To carry out a Phase III randomized trial of intermediate dose intraperitoneal cis-platinum plus intravenous cyclophosphamide versus intermediate dose intravenous cis-platinum plus intravenous cyclophosphamide for optimal Stage III ovarian cancer.

2. To evaluate the toxicities and complications of the two combination drug regimens.

3. To determine in the setting of a respective randomized trial if the human tumor clonogenic assay with a wide range of drug concentration testing can accurately predict pathologic complete response to two-drug combination therapy in the setting of systemic and intraperitoneal drug administration.

**Technical Approach:** Patients must have a histologically confirmed diagnosis of ovarian carcinoma. Only patients without prior cytotoxic chemotherapy will be eligible for this protocol.

Therapy will follow the schema outlined in the study protocol.

**Progress:** Study closed March 1993.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: GOG 107      Status: Completed

Title: A Randomized Study of Doxorubicin vs Doxorubicin Plus Cisplatin in Patients with Primary Stage III and IV, Recurrent Endometrial Adenocarcinoma, Phase III.

Start date: 25 Jul 90	Estimated completion date:
Principal Investigator: Allan R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine whether the addition of cisplatin to doxorubicin offers significant improvement in the frequency of objective response, the duration of progression-free interval, and the length of survival as compared to doxorubicin alone.

Technical Approach: All patients with histologically documented primary Stage III or Stage IV, or recurrent endometrial adenocarcinoma, adenoacanthoma, or adenosquamous carcinoma whose potential for cure by radiation therapy or surgery alone or in combination is very poor will be eligible. Measurements by sonography and/or CT scans are acceptable if the mass is sharply defined.

Therapy will follow the schema outlined in the study protocol.

Progress: Study closed March 1993.

**Detail Summary Sheet**

Date: 31 Dec 93

Protocol Number: GOG 108

**Status:** Ongoing

**Title: Ifosfamide (NSC#109724) and the Uroprotector Mesna (NSC#113891) With or Without Cisplatin (NSC#119875) in Patients with Advanced, Persistent or Recurrent Mixed Mesodermal Tumors of the Uterus (Phase III)**

Start date: 21 Sep 92	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

**Objective(s):** 1) To confirm reported high response rates of advanced or recurrent mixed mesodermal tumors of the uterus to ifosfamide/Mesna. 2) To determine whether the addition of Cisplatin to Ifosfamide/Mesna improves response rates or survival in patients with these tumors. 3) To determine the toxicity of Ifosfamide/Mesna with Cisplatin in patients with these tumors.

**Technical Approach:** Patient will be hydrated prior to institution of therapy with 1000 cc of normal or one-half normal saline at a rate to maintain urine output at greater than 100 cc/hour. Patients randomized to Ifosfamide without platinum therapy will be instituted with bolus of Mesna 120 mgm/m<sup>2</sup> 15 minutes prior to the Ifosfamide. Ifosfamide will be administered. After completing the Ifosfamide, the Mesna will be administered by continuous infusion over five days uninterrupted except on subsequent days when Ifosfamide is administered. For patients receiving Cisplatin, platinum administration will precede the Ifosfamide therapy and should be reconstituted to concentration of approximately 1 mgm/cc and infused at a rate of 1 mgm/min.

Progress: Study remains open for data accrual.

**Detail Summary Sheet**

**Date:** 31 Dec 93

**Protocol Number:** GOG 109

**Status:** Ongoing

**Title:** A Randomized Comparison of 5-FU Infusion and Bolus Cisplatin as an Adjunct to Radiation Therapy, Versus Radiation Therapy Alone in Selected Patients with Stages I-A2, I-B, and II-A Carcinoma of the Cervix Following Radical Hysterectomy and Node Dissection

Start date: 16 Mar 92	Estimated completion date:
Principal Investigator: LTC Allan R. Mayer, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: Review results:

**Objective(s):** 1) To determine whether the combination of 5-fluorouracil (5-FU) and cisplatin used as an adjunct to radiation therapy will improve survival rate or progression-free survival and decrease extra pelvic failure compared to radiation therapy alone in patients with positive pelvic lymph nodes, positive parametrial involvement or positive surgical margins following radical hysterectomy and lymph node dissection for Stages I-A2, I-B and II-A carcinoma of the cervix. 2) To determine the increase in toxicities due to 5-FU and cisplatin as an adjunct to radiation therapy versus radiation therapy alone.

**Technical Approach:** All eligible patients will receive therapy as outlined in the study protocol.

**Progress:** Study remains open for data accrual.

**Detail Summary Sheet**

**Date:** 31 Dec 93

**Protocol Number:** GOG 110

**Status:** Ongoing

**Title:** A Randomized Comparison of Cisplatin Versus Cisplatin Plus Dibromodulcitol (NSC#104800) Versus Cisplatin Plus Ifosfamide and Mesna in Advanced Carcinoma of the Cervix

<b>Start date:</b> 16 Mar 92	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> LTC Allan R. Mayer, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Obstetrics and Gynecology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 0

**Total number of subjects enrolled to date:** 0

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) To determine if mitolactol plus cisplatin or ifosfamide plus cisplatin improves response rate, response duration, progression-free interval and/or survival in advanced squamous cervical cancer compared to cisplatin alone. 2) To compare the toxicity of these three regimens in advanced cervical cancer.

**Technical Approach:** Patients will be stratified according to whether or not they have had prior cisplatin as a radiation sensitizer and by performance status. Under Regimen I, cisplatin 50 mg/m<sup>2</sup> with hydration will be repeated every three weeks and treatment will continue until disease progresses or until toxicity prohibits further therapy or for a maximum of six courses. Regimen II will include cisplatin plus dibromodulcitol (mitolactoll), DBD) and treatment will continue until toxicity prohibits further or for a maximum of six courses. Regimen III will include cisplatin plus ifosfamide (plus mesna). Cisplatin 50 mg/m<sup>2</sup> with hydration per GOG guideliens plus ifosfamide 5.0 grams/m<sup>2</sup> in 1 liter of dextrose and saline over 24 hrs plus mesna 6 grams/m<sup>2</sup> will be given concurrently with ifosfamide and for 12 hrs after every 3 weeks. Mesna should be given as 2 gm/m<sup>2</sup> in 1 liter of dextrose/saline or normal saline every 12 hours as a separate infusion which can be "piggy-backed" into the intravenous line for the ifosfamide.

**Progress:** Study remains open for data accrual.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: GOG 111      Status: Completed

Title: A Phase III Randomized Study of Cyclophosphamide and Cisplatin vs Taxol and Cisplatin in Patients with Suboptimal Stage III and IV Epithelial Ovarian Carcinoma.

Start date: 25 Jul 90	Estimated completion date:
Principal Investigator: Allan R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 5

Total number of subjects enrolled to date: 5

Periodic review date: Review results:

Objective(s): 1) To determine response rate, response duration and survival in suboptimal Stage III and Stage IV ovarian cancer treated with two different platinum-based combination chemotherapy regimens.

2) To evaluate the relative activity and toxicities of a new combination, cisplatin/taxol, as compared to the standard regimen, cisplatin/cyclophosphamide

Technical Approach: Patients with established ovarian epithelial cancer, suboptimal Stage III and Stage IV will be eligible. All patients must have optimal surgery for ovarian cancer, with at least exploratory laparotomy and appropriate tissue submitted for histologic examination.

Therapy will follow the schema outline in the study protocol.

Progress: Study closed March 1993.

**Detail Summary Sheet**

**Date:** 31 Dec 93      **Protocol Number:** GOG 112      **Status:** Ongoing

**Title:** A Randomized Comparison of Chemoprophylaxis Using Methotrexate Versus Routine Surveillance in the Management of the High Risk Molar Pregnancy.

<b>Start date:</b> 15 Apr 91	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> MAJ Kevin Hall, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Obstetrics and Gynecology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 4

**Total number of subjects enrolled to date:** 5

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) To determine the incidence of post molar trophoblastic disease after evacuation of the high risk molar pregnancy in those patients receiving chemoprophylaxis versus those randomized to usual post evacuation surveillance.

2) To evaluate the toxicity associated with chemoprophylaxis.

3) To develop a clinical pathologic scoring system for risk of postmolar trophoblastic disease which highly correlates with the serum free beta HCG assay.

**Technical Approach:** As outlined in the study protocol.

**Progress:** Data results of the previously enrolled patients are currently not available.

Detail Summary Sheet

Date: 31 Dec 93

Protocol Number: GOG 114

Status: Ongoing

Title: A Phase II Randomized Study of Intravenous Cisplatin and Cyclophosphamide Versus Intravenous Cisplatin and Taxol Versus High Dose Intravenous Carboplatin Followed by Intravenous Taxol and Intraperitoneal Cisplatin in Patients with Optimal Stage III Epithelial Ovarian Carcinoma

Start date: Jun 92	Estimated completion date:
Principal Investigator: LTC Allan R. Mayer, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: Review results:

Objective(s): 1) To compare recurrence-free interval, complete pathologic response, and survival between the standard regimen: intravenous cisplatin/cyclophosphamide and the two experimental regimens: Intravenous cisplatin/taxol and intravenous carboplatin followed by intravenous taxol and intraperitoneal cisplatin in patients with optimal (< 1 cm residual) stage III epithelial ovarian carcinoma. 2) To compare the toxicities and complications of the three treatment regimens. 3) To correlate serial serum CA-125 levels with negative second look and recurrence-free interval.

Technical Approach: Therapy will be administered as outlined in the study protocol.

Progress: Study remains open for data accrual.

**Detail Summary Sheet**

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**Date:** 31 Dec 93      **Protocol Number:** GOG 115      **Status:** Completed

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**Title:** Bleomycin, Etoposide and Cisplatin as First Line Therapy of Malignant Tumors of the Ovarian Stroma (Granulosa Cell, Sertoli-Leydig Tumor, and Unclassified Sex Cord Stromal Tumor).

<b>Start date:</b> 20 May 91	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Allen R. Mayer, LTC, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Obstetrics and Gynecology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

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**Number of subjects enrolled during reporting period:** \_\_\_\_\_  
**Total number of subjects enrolled to date:** \_\_\_\_\_  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** To assess the efficacy of bleomycin, etoposide (VP-16), and cisplatin (BEP) chemotherapy in patients with malignant tumors of the ovarian stroma of the ovary as a first-line regimen.

**Technical Approach:** Therapy will follow the schema outlined in the study protocol.

**Progress:** Study closed March 1993.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: GOG 116      Status: Completed

Title: Evaluation of Adjuvant VP-16 and Carboplatin Therapy in Totally Resected Ovarian Dysgerminoma.

Start date: 20 May 91	Estimated completion date:
Principal Investigator: Allen R. Mayer, LTC, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To evaluate the effect of adjuvant VP-16 and carboplatin chemotherapy in patients with completely resected ovarian dysgerminoma.

2) To evaluate the acute and chronic toxicity of this chemotherapy on gonadal and reproductive function.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study closed March 1993.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: GOG 117      Status: Ongoing

Title: Adjuvant Ifosfamide and Mesna with Cisplatin in Patients with Completely Resected Stage I or II Mixed Mesodermal Tumors of the Uterus.

Start date: 22 Jul 91	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: Review results:

Objective(s): 1) To determine whether cisplatin and ifosfamide/mesna can determine the recurrence rate in patients with completely resected stage I or II mixed mesodermal tumors of the uterus.

2) To determine whether postoperative chemotherapy is more effective than surgery alone in local (pelvic) control of these tumors.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study remains open for patient enrollment.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: GOG 118      Status: Ongoing

Title: Evaluation of the Predicted Value of antineoplastic Drug Resistance Determined by in vitro Assay.

Start date: 22 Jul 91	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: Review results:

Objective(s): To evaluate the correlation between response to chemotherapy and in vitro drug resistance assessed by two laboratory endpoints (cytostatic and cytocidal) in untreated epithelial ovarian carcinoma.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study remains open for patient enrollment.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: GOG 119      Status: Ongoing

Title: A Study of the Use of Provera and Nolvadex for the Treatment of Advanced, Recurrent, or Metastatic Endometrial Cancer.

Start date: 22 Jul 91	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: Review results:

Objective(s): 1) To determine the efficacy of tamoxifen citrate plus intermittent administration of Provera<sup>®</sup> (Medroxyprogesterone Acetate) in patients with recurrent or metastatic endometrial carcinoma.

2) To determine the side effects of such treatment in patients with this disease.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Study remains open for patient enrollment.

**Detail Summary Sheet**

**Date:** 31 Dec 93

**Protocol Number:** GOG 120

**Status:** Ongoing

**Title:** A Randomized Comparison of Hydroxyurea Versus Hydroxyurea, 5-FU Infusion and Bolus Cisplatin Versus Weekly Cisplatin as Adjunct to Radiation Therapy in Patients with Stages II-B, III, and IV-A Carcinoma of the Cervix and Negative Para-Aortic Nodes

<b>Start date:</b> 20 Apr 92	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> MAJ Kevin Hall, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Obstetrics and Gynecology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 0

**Total number of subjects enrolled to date:** 0

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) To determine whether hydroxyurea, hydroxyurea, 5-FU infusion and bolus cisplatin, or weekly cisplatin is superior as a potentiator of radiation therapy in locally advanced cervical carcinoma. 2) To determine the relative toxicities of hydroxyurea, hydroxyurea, 5-FU infusion and bolus cisplatin, or weekly cisplatin given concurrently with radiation therapy.

**Technical Approach:** Patients with untreated cervical carcinoma Stages II-B, III-A, III-B and IV-A, who have fulfilled the eligibility requirements according to Section 3.0 will receive pelvic radiotherapy as outlined and will be randomized according to regimens outlined in study protocol.

**Progress:** Study remains open for data accrual.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: GOG 121      Status: Ongoing

Title: A Phase II Trial of High Dose Megestrol Acetate (Megace) in Advanced or Recurrent Endometrial Carcinoma

Start date: 21 Oct 91	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date:      Review results:

Objective(s): 1) To determine the response rate and progression-free interval in patients receiving high dose megestrol acetate (Megace) for advanced or recurrent endometrial carcinoma. 2) To determine the toxicity of high dose megestrol acetate in such patients. 3) To determine if estrogen/progesterone receptor status is predictive of response.

Technical Approach: Patients will take orally two tablets at breakfast, two tablets at lunch and one tablet at dinner for a total daily dose of 800 mg. Therapy will continue as outlined in the study protocol.

Progress: Study remains open for data accrual.

Detail Summary Sheet

Date: 31 Dec 93

Protocol Number: GOG 122

Status: Ongoing

Title: Whole Abdominal Radiotherapy Versus Circadian-Timed Combination Doxorubicin-Cisplatin Chemotherapy in Advanced Endometrial Carcinoma

Start date: 19 Nov 91	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: Review results:

Objective(s): 1) To compare treatment outcomes (survival and progression-free interval) and failure patterns in patients with stages II-IV endometrial carcinoma (< 2 cm residual disease) treated with whole abdominal irradiation versus combination doxorubicin-cisplatin chemotherapy. 2) To determine and compare the incidence and type of acute and late adverse events observed with the two treatment regimens.

Technical Approach: Therapy will be administered as outlined in the study protocol.

Progress: Study remains open for data accrual.

**Detail Summary Sheet**

**Date:** 31 Dec 93      **Protocol Number:** GOG 123      **Status:** Ongoing

**Title:** A Randomized Comparison of Radiation Therapy and Adjuvant Hysterectomy in Patients with Bulky Stage IB Carcinoma of the Cervix, Phase III

<b>Start date:</b> 19 Nov 91	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> MAJ Kevin Hall, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Obstetrics and Gynecology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 0

**Total number of subjects enrolled to date:** 0

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) To determine if weekly cisplatin infusion improves local regional control and survival when added to radiation therapy plus extrafascial hysterectomy. 2) To determine the relative toxicities of these two treatment arms.

**Technical Approach:** In this study, we plan to compare the addition of weekly cisplatin infusion with current apparent better arm of Protocol #71; radiation therapy plus adjuvant hysterectomy in patients with bulky Stage IB carcinoma of the cervix.

**Progress:** Study remains open for data accrual.

**Detail Summary Sheet**

**Date:** 31 Dec 93      **Protocol Number:** GOG 125      **Status:** Ongoing

**Title:** Extended Field Radiation Therapy with Concomitant 5-FU Infusion and Cisplatin Chemotherapy in Patients with Cervical Carcinoma Metastatic to Para-aortic Lymph Nodes, Phase II

Start date: 27 Jan 92	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

**Objective(s):** Patients with uterine cervical carcinoma who have biopsy confirmed para-aortic lymph node metastases will receive combination chemotherapy consisting of cisplatin and 5-FU intravenous infusion concomitantly with pelvic and para-aortic extended field radiation therapy.

**Technical Approach:** All patients with primary, previously untreated, histologically confirmed, invasive carcinoma of the uterine cervix (squamous, adenosquamous and adenocarcinoma and all clinical stages (except clinical Stage 111A and IVB), with metastasis to para-aortic lymph nodes proven by cytologic or histologic means will receive therapy as outlined in the study protocol.

**Progress:** Study remains open for data accrual.

**Detail Summary Sheet**

**Date:** 31 Dec 93      **Protocol Number:** GOG 132      **Status:** Ongoing

**Title:** A Phase III Trial of Taxol at Three Dose Levels and G-CSF at Two Dose Levels in Platinum-Resistant Ovarian Carcinoma

<b>Start date:</b> 18 May 92	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> MAJ Kevin Hall, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Obstetrics and Gynecology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** 0

**Total number of subjects enrolled to date:** 0

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) To determine the relative efficacy of regimens consisting of taxol versus cisplatin versus a combination of the two drugs in patients with suboptimally debulked stage III & IV epithelial ovarian cancer. 2) To determine which of the three regimens contribute most favorably to progression-free interval and survival. 3) To compare the incidence of audiologic sequelae and other toxicities arising from any of the three regimens.

**Technical Approach:** Once patient eligibility is determined, therapy will continue as outlined in study protocol.

**Progress:** Study remains open for data accrual.

**Detail Summary Sheet**

**Date:** 31 Dec 93      **Protocol Number:** GOG 134      **Status:** Ongoing

**Title:** Evaluation of Drug Sensitivity and Resistance with the ATP-Cell Viability Assay (ATP-CVA)

Start date: 18 May 92	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: Review results:

**Objective(s):** 1) To determine if the dose of taxol affects response rate, progression-free interval or survival in patients with platinum-resistant ovarian cancer. 2) To compare the toxicities of the three regimens. 3) To compare the efficacy and toxicity of two dose levels of G-CSF (5 ug/kg/day versus 10 ug/kg/day) in patients who receive the highest taxol dose (250 mg/m<sup>2</sup>). 4) To determine the relationship between peak taxol plasma concentration and toxicity/response.

**Technical Approach:** Patients with platinum-resistant ovarian epithelial cancer stage III and stage IV will receive therapy as outlined in the study protocol.

**Progress:** Study remains open for data accrual.

**Detail Summary Sheet**

Date: 31 Dec 93

Protocol Number: GOG 135

**Status:** Ongoing

**Title: Evaluation of Drug Sensitivity and Resistance with the ATP-Cell Viability Assay (ATP-CVA)**

Start date: 18 May 92	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

**Objective(s):** 1) To evaluate the correlation between the ATP-cell viability assay (ATP-CVA) and patient response to chemotherapy in untreated primary epithelial ovarian carcinoma. 2) To correlate laboratory results with the achievement of Pathologic CR at time of 2nd look surgery. 3) To correlate laboratory results with progression-free survival. 4) To correlate single agent and combined agent in vitro studies with clinical outcome.

**Technical Approach:** Patients with primary ovarian epithelial carcinoma who are eligible will receive therapy as outlined in study protocol.

Progress: Study remains open for data accrual.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: GOG 136      Status: Ongoing

Title: Acquisition of Human Ovarian and Other Tissue Specimens and Serum to be Used in Studying the Causes, Diagnosis, Prevention and Treatment of Cancer

Start date: 22 Jun 92	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: Review results:

Objective(s): 1) To accomplish the collection of human ovarian tissue specimens and serum within GOG participating institutions. 2) To provide a repository for long-term storage of ovarian tumor, tissue and serum. 3) To make available through the Cooperative Human Tissue Network (CHTN), tumor tissue and serum for proposed projects conducted by GOG Investigators (internal bank) and by researchers nationally (external bank).

Technical Approach: All eligible patients who have had ovarian tumor tissue removed including all epithelial tumors, germ cell, sex cord stromal and other primary ovarian malignancies will receive therapy as outlined in the study protocol.

Progress: Study remain in for data accrual.

Detail Summary Sheet

Date: 31 Dec 93

Protocol Number: GOG 138

Status: Ongoing

Title: A Phase II Trial of Cisplatin and Cyclophosphamide in the Treatment of Extraovarian Peritoneal Serous Papillary Carcinoma

Start date: 21 Sep 92	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 0

Total number of subjects enrolled to date: 0

Periodic review date: Review results:

Objective(s): To determine the response rate, and response duration in patients with extraovarian peritoneal serous papillary carcinoma treated with a combination of cisplatin and cyclophosphamide.

Technical Approach: Once patient has been determined eligible, treatment will initiated as outlined in the study protocol.

Progress: Study remains open for data accrual.

**Detail Summary Sheet**

**Date:** 31 Dec 93      **Protocol Number:** GOG 8803      **Status:** Completed

**Title:** Flow Cytometrically Determined Tumor DNA Content in Advance Epithelial Ovarian Cancer.

<b>Start date:</b> 25 Jul 90	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Allen R. Mayer, LTC, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Obstetrics and Gynecology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_

**Total number of subjects enrolled to date:** \_\_\_\_\_

**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) Can tumor ploidy and cell proliferation be correlated to accepted tumor and host factors, including patient age, tumor histology and grade, stage and amount of residual disease?

2) Can tumor ploidy and cell proliferation be correlated to tumor response, second look laparotomy findings, relapse and survival?

3) Are tumor ploidy and cell proliferation consistent between primary and metastatic sites and stable before and after combination chemotherapy?

**Technical Approach:** Paraffin blocks from both the primary ovarian tumor as well as 1 to 3 metastatic sites will be analyzed to look at the inter-tumor variability. When one or more paraffin-embedded tumor blocks have been obtained, specimens for flow cytometric determination of tumor cell DNA content and, if possible, cell cycle distribution will be prepared by the modified method of Hedley.

**Progress:** Study closed March 1993.

Detail Summary Sheet

Date: 31 Dec 93      Protocol Number: GOG 8809      Status: Completed

Title: Flow Cytometrically Determined Tumor DNA Content in Ovarian Tumors of Low Malignant Potential.

Start date: 25 Jul 90	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics and Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: 1

Total number of subjects enrolled to date: 2

Periodic review date:      Review results:

Objective(s): To determine whether the DNA content of borderline ovarian tumors (carcinoma of low malignant potential) can be correlated with extent/stage of tumor, potential for recurrence, and patient survival.

Technical Approach: Paraffin blocks from both the primary ovarian tumor as well as any metastatic site will be analyzed to look at the inter-tumor variability. When one or more paraffin-embedded tumor blocks have been obtained, specimens for flow cytometric determination of tumor cell DNA content and, if possible, cell cycle distribution will be prepared by the modified method of Hedley.

Progress: Study closed.

**Detail Summary Sheet**

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**Date:** 31 Dec 93      **Protocol Number:** GOG 8810      **Status:** Completed

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**Title:** Flow Cytometrically Determined Tumor DNA Content in Endometrial Carcinoma.

<b>Start date:</b> 25 Jul 90	<b>Estimated completion date:</b>
<b>Principal Investigator:</b> Allan R. Mayer, LTC, MC	<b>Facility:</b> Brooke Army Medical Center, Texas
<b>Department/Service:</b> Department of Obstetrics and Gynecology	<b>Associate Investigator(s):</b>
<b>Key Words:</b>	
<b>Cumulative MEDCASE cost:</b>	<b>Estimated cumulative OMA cost:</b>

**Number of subjects enrolled during reporting period:** \_\_\_\_\_  
**Total number of subjects enrolled to date:** \_\_\_\_\_  
**Periodic review date:** \_\_\_\_\_ **Review results:** \_\_\_\_\_

**Objective(s):** 1) To determine the DNA content of primary, recurrent and metastatic endometrial adenocarcinoma, and identify whether the presence of aneuploid cell populations is related to histologic cell type, histologic grade or stage of disease.  
 2) To determine whether tumor ploidy is related to the probability of lymph node resistant metastasis, extended progression free interval, or five year survival.  
 3) To determine whether tumor ploidy is consistent when primary tumors are compared with their metastases.

**Technical Approach:** Paraffin blocks containing material representative of the primary endometrial adenocarcinoma from either hysterectomy or D&C specimen may be submitted. A minimum surface area of tumor of not less than 1 cm<sup>2</sup> should be present in the block to assure sufficient neoplasm for flow cytometric studies to be conducted. If metastatic tumor is present in either pelvic or para-aortic lymph nodes, or distant sites, then a block from these sites should also be submitted, if possible. When one or more paraffin-embedded tumor blocks have been obtained, specimens for flow cytometric determination of tumor cell DNA content and, if possible, cell cycle distribution will be prepared by the modified method of Hedley.

**Progress:** Study closed March 1993.

**Detail Summary Sheet**

Date: 15 Dec 93

Protocol Number: GOG 26 NN

**Status: Completed**

**Title: A Phase II Trial of Piroxantrone in Patients with Advanced & Recurrent Ovarian Epithelial Carcinoma**

Start date:	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

**Number of subjects enrolled during reporting period:**

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: Review results:

**Objective(s):** To evaluate a succession of new agents (cytotoxic drugs, hormones, biologic response modifiers) in a fair and efficient manner, identify active agents and provide the group with this information so that more effective regimens for the treatment of ovarian cancer can be developed.

**Technical Approach:** We intend to search for activity of new agents or drug combinations in patients with advanced or recurrent pelvic malignancies. There are no treatment comparisons involved and no known historical controls available. It is felt that recognition of a 15-20% response rate for a given plan of therapy would constitute a significant finding. Therapy plans demonstrating activity will later be compared and investigated in ensuing Phase III studies.

Progress: This protocol was closed to entry 6/7/93.

Detail Summary Sheet

Date: 15 Dec 93

Protocol Number: GOG 86-A

Status: Ongoing

Title: Phase II Drug Studies in Treatment of Advanced or Recurrent Carcinoma of the Endometrium

Start date:	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To identify additional active agents by studying single new drugs in patients with advanced or recurrent endometrial carcinoma not previously exposed to chemotherapy. Approximately 30 evaluable patients will be accrued for each drug studies, this will allow reasonable estimates of response rates.

Technical Approach: As outlined in the study protocol.

Progress: 86A remains the master program for a series of endometrial studies. Currently out to 86-O. It is still open.

Detail Summary Sheet

Date: 15 Dec 93

Protocol Number: GOG 87-D

Status: Ongoing

Title: A Phase II Trial of VP-16 in Patients with Advanced or Recurrent Uterine Sarcomas

Start date:	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To indicate the need for identification of new agents and combinations for treating this malignancy. To allow the best possible chance for a new cytotoxic agent to demonstrate activity, this study constitutes a Phase II design in a population of patients who have had no prior drug therapy.

Technical Approach: The study design involves treating an average sample size of 30 evaluable patients per drug studied for each of the following cell type categories: mixed mesodermal tumor, leiomyosarcoma, and other sarcomas. Sections relating to specific agents will be sequentially incorporated into this protocol as each agent is studied.

Progress: This protocol remains open for patient entry. No patients have as yet been enrolled.

Detail Summary Sheet

Date: 15 Dec 93      Protocol Number: GOG 126-B      Status: Ongoing

Title: Evaluation of Cisplatin & Cyclosporin in Recurrent, Platinum Resistant & Refractory Ovarian Cancer

Start date:	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_  
Total number of subjects enrolled to date: \_\_\_\_\_  
Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To estimate the antitumor activity of cisplatin and cyclosporin in patients with recurrent, platinum-resistant or refractory ovarian cancer who have failed on higher priority treatment protocols. 2) To determine the nature and degree of toxicity of cisplatin and cyclosporin in this cohort of patients.

Technical Approach: As outlined in the study protocol.

Progress: This protocol remains open for patient entry. No enrollments have occurred to date.

Detail Summary Sheet

Date: 15 Dec 93

Protocol Number: GOG 129-B

Status: Ongoing

Title: A Phase II Trial of Prolonged Oral Etoposide (VP-16) in the Treatment of Recurrent or Advanced Endometrial Carcinoma

Start date:	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To estimate the antitumor activity of oral VP-16 in patients with metastatic or advanced endometrial carcinoma who have failed on higher priority treatment protocols. 2) To determine the nature and degree of toxicity of oral VP-16 in this cohort of patients

Technical Approach: As outlined in the study protocol.

Progress: This protocol remains open to patient entry. No patients have been enrolled to date.

Detail Summary Sheet

Date: 15 Dec 93      Protocol Number: GOG 137      Status: Ongoing

Title: A Randomized Trial of Estrogen Replacement Therapy Versus no Estrogen Replacement in Women with Stage I or II Endometrial Adenocarcinoma

Start date:	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): To determine the effect of estrogen replacement therapy on recurrence-free and overall survival in women with a history of stage I or II endometrial adenocarcinoma.

Technical Approach: As outlined in the study protocol.

Progress: This protocol remains open to patient entry.

Detail Summary Sheet

Date: 15 Dec 93

Protocol Number: GOG 139

Status: Ongoing

Title: A Randomized Study of Doxorubicin Plus Cisplatin Versus Circadian-timed Doxorubicin Plus Cisplatin in Patients with Primary Stage III & IV, Recurrent Endometrial Adenocarcinoma

Start date:	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) To determine if circadian-timed doxorubicin-cisplatin chemotherapy offers significant improvement in the frequency of objective response, the duration of progression-free interval, and the length of survival as compared to standard doxorubicin-cisplatin chemotherapy. 2) To determine if there are any significant differences in toxicity between circadian-timed delivery of doxorubicin-cisplatin chemotherapy versus standard delivery of doxocurbin-cisplatin chemotherapy.

Technical Approach: As outlined in the study protocol.

Progress: This protocol remains open for patient entry. One patient has been enrolled to date.

Detail Summary Sheet

Date: 15 Dec 93      Protocol Number: GOG 143      Status: Ongoing

Title: Familial and Reproductive Factors in Ovarian Cancer

Start date:	Estimated completion date:
Principal Investigator: MAJ Kevin Hall, MC	Facility: Brooke Army Medical Center, Texas
Department/Service: Department of Obstetrics/Gynecology	Associate Investigator(s):
Key Words:	
Cumulative MEDCASE cost:	Estimated cumulative OMA cost:

Number of subjects enrolled during reporting period: \_\_\_\_\_

Total number of subjects enrolled to date: \_\_\_\_\_

Periodic review date: \_\_\_\_\_ Review results: \_\_\_\_\_

Objective(s): 1) Compute prevalence rates for cancer of the ovary, breast, colon and uterus in first- and second-degree relatives of ovarian cancer cases. 2) Identify that subset of multicase families who would be candidates for linkage analysis studies in the companion GOG Protocol 144. 3) Estimate by fitting major gene models to familial ovarian cancer incidence. 4) Determine if established reproductive risk factors (parity, oral contraceptive (OC) use, tubal ligation) after risk in women with a positive family history. 5) To collect and store a blood sample from each participant in the study for storage and subsequent gene frequency analysis.

Technical Approach: As outlined in the study protocol.

Progress: This protocol remains open per GOG. We have not yet approved the consent-pending my attendance at the review board.